

28.0 Informed Consent

Informed consent is a process rather than merely a document. Any individual invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process should be designed to provide potential subjects with readily understandable information in an amount and timing appropriate to the level of risk in participating. The circumstances of the consent process should minimize the possibility of coercion or undue influence.

The subject's consent must follow and not precede receipt of this information unless the IRB approves a waiver or alteration of informed consent (as in some behavioral research that would be compromised by full disclosure in advance). Consent must be obtained from each subject who is legally, mentally, and physically able to provide it unless waived by the IRB. Consent should be in writing unless the IRB finds that written documentation of informed consent may be waived. Consent forms and other informational documents should be written in simple language so as to be easily understood by persons with no technical background in the field.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The standard expectation is that all subjects will sign a document containing all the elements of informed consent, as specified in the federal regulations and noted below. Some or all of the elements of consent, including signatures, may be waived under certain circumstances.

As stated in SOP 24.4, the IRB has the authority to observe or have a third party observe the consent process and the research (as allowed under 45 CFR 46.109(e)).

28.1 Basic elements of informed consent

Unless the IRB approves exceptions, the following information must be provided to the subject when seeking informed consent:

- 28.1.1 A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
 - 28.1.2 A description of any reasonably foreseeable risks or discomforts to the subject;
 - 28.1.3 A description of any benefits to the subject or to others that may be reasonably expected from the research;
 - 28.1.4 A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
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- 28.1.5 A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained; (see SOP 29.0 HIPPA and IRB Review and SOP 24.6 Privacy of Subjects and Confidentiality of Data). For FDA-regulated research, a statement that notes the possibility that the FDA might inspect the records.
 - 28.1.6 For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
 - 28.1.7 An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.
 - 28.1.8 A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- 28.2 Additional elements of informed consent
- For some studies, one or more of the following elements or information may be appropriate and required by the IRB:
- 28.2.1 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) that are currently unforeseeable;
 - 28.2.2 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - 28.2.3 Any additional costs to the subject that may result from participation in the research;
 - 28.2.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (particularly when potentially therapeutic experimental interventions are being administered and unscheduled cessation of the intervention may pose health risks to subjects);
 - 28.2.5 A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
 - 28.2.6 The approximate number of subjects involved in the study.
 - 28.2.7 The amount and schedule of payments, if any.
- 28.3 Exceptions to informed consent requirements

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

28.3.1 The research or demonstration project is to 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 of service programs; (45 CFR 46.116(c)(1)(i))
- procedures for obtaining benefits or services under those programs; (45 CFR 46.116(c)(1)(ii))
- possible changes in or alternatives to those programs or procedures; or (45 CFR 46.116(c)(1)(iii))
- possible changes in methods or levels of payment for benefits or services under those programs; and (45 CFR 46.116(c)(1)(iv))
- The research could not practicably be carried out without the waiver or alteration. (45 CFR 46.116(c)(2))

For research using protected health information (PHI), see SOP 29.3 for additional criteria for waiver or modification of the HIPAA requirement for written authorization.

28.4 Other exceptions to informed consent requirements 45 CFR 46.116(d)

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:

28.4.1 The research involves no more than minimal risk to the subjects;

28.4.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;

28.4.3 The research could not practicably be carried out without the waiver or alteration;

28.4.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

These exceptions do not apply to FDA-regulated research.

For research using PHI, see SOP 29.3 for additional criteria for waiver or modification of the HIPAA requirement for written authorization

28.5 Other information concerning informed consent

28.5.1 The informed consent requirements in this policy are not intended to preempt any applicable federal, State, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

28.5.2 Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, State, or local law.

28.6 Short form consent procedures

There may be circumstances when a subject is unable to read the full consent document (e.g., when the subject is illiterate or does not speak the language in which the consent document is written). In most circumstances, the IRB expects that a translation of the full form will be provided. However, there may be times when there is no opportunity to prepare a long form in advance; in such cases, a short form may be used.

The short form is not to be used when a study team has simply failed to make provisions for translated versions of the consent document in commonly spoken languages in the recruitment area/population.

A short form is a written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Under many circumstances the full consent form may serve as this written summary. Only the short form itself is to be signed and dated by the subject or the legally authorized representative. However, the witness shall sign (and date for FDA-regulated research) both the short form and a copy of the summary, and the person actually obtaining consent shall sign (and date for FDA-regulated research) a copy of the summary. A copy of the signed (and dated for FDA-regulated research) summary shall be given to the subject or the representative, in addition to a copy of the signed (and date for FDA-regulated research) and short form.

28.7 Waiver of written consent

The IRB may waive the requirement for the investigator to obtain a signed consent form in cases where circumstances warrant such a waiver. Such a waiver is allowable if:

- The consent document is the only link between the subject and the research and the principal risk of harm would come 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 [45 CFR 46.117 (d)(1)]
- The research presents no more than a minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context. [45 CFR 46.117 (d)(2)]

In lieu of a signed consent form the IRB may require the investigator to provide subjects with a written statement regarding the research in the form of an information or fact sheet. This information will be reviewed by the IRB. The written statement should contain, at a minimum:

- A statement that the project involves research;
- A description of the level of involvement and amount of time expected from subjects;
- A description of the study
- A description of the risks and benefits to subjects;
- A statement describing the subject's rights;

- A description of the compensation to be provided to subjects;
- Contact information for both the investigator and the IRB.

Examples of circumstances in which a waiver of written consent may be considered include situations where the researcher plans to use an abbreviated consent process, as in recruiting passersby for a brief, minimal risk survey. Similarly, a waiver may be granted to allow researchers to obtain oral consent for a telephone survey. Finally, a waiver may also be granted if researchers want subjects to imply their consent by returning a survey via the mail or the internet. This last approach is especially useful in preserving the anonymity of the subjects surveyed. For research using PHI, see SOP 29.3 on the additional criteria for waiver or modification of the HIPAA requirement for written authorization

28.7.1 Waiver of written consent does not apply to FDA-regulated studies.

28.8 UNC-Chapel Hill consent form templates

In most cases the IRB requires that the Consent Form templates available via the Internet be used for all written consent form documents. This consent template contains all of the basic elements described above. For clarity and to assure timely processing by the IRB, the consent form should follow the guidelines described below.

The consent form and study fact sheet must be written at a level understandable to all potential participants and it must contain all information that would reasonably inform the subject's willingness to participate. In order to facilitate this requirement, the IRB will provide templates that reflect appropriate language for various subject populations. The consent form should be written in second person with "you" or "your child" consistently used to refer to the subject in all statements.

In most cases, the title of the project as listed on the consent form should be the same as the title listed on the application form, though the IRB may suggest or require modifications in the title under certain circumstances (e.g., in case the title would alert subjects to deception in the study or when the title may be too explicit regarding subject criteria as in a study of dysfunctional parents).

The date on which the consent form was prepared or modified should be indicated on the form, (See Appendix F), so that revised forms can be easily distinguished from prior versions.

28.9 Assent by children

Except under specific circumstances, assent to participate in a study must be obtained from children (i.e., in North Carolina, subjects aged 17 and under) who are capable of providing assent, which can be written, oral or both. The IRB shall determine that adequate provisions are made for soliciting the assent of the children (this includes providing age specific language to the prospective subjects), when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child individually, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children (such as in a study with therapeutic potential), and is

available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116.

When assent is a requirement, the IRB will determine whether assent is to be documented. When assent is to be documented, the IRB will review the process to be used.

28.9.1 Special issues in consent involving older children

Principal investigators are required to seek the consent of a child's parent or guardian before enrolling a child in a study and beginning treatment and/or conducting research. North Carolina statutes do not address consent for research; however, IRBs and investigators should be aware that under North Carolina state law, a child can consent to medical treatment when he/she is emancipated or when the services are for the "prevention, diagnosis and treatment of (i) venereal disease and other diseases reportable under North Carolina law (ii) pregnancy, (iii) abuse of controlled substances or alcohol, and (iv) emotional disturbance."

In certain cases, limited to those described below, the assent of children may, by itself, represent informed consent. Most children, however, must assent in tandem with parental permission. The special circumstances, which will be reviewed on a case-by-case basis by the IRB, include:

- Minors emancipated via court petition (In North Carolina, emancipated minors must be at least 16 years of age and must petition the courts for emancipation. Pregnancy or parenthood does not automatically emancipate a minor (See Appendix L). For children who are pregnant, assent and permission will be obtained in accordance with the regulations;
- University students under the age of 18;
- Minors who are legally married;
- Minors serving in the armed forces of the United States; or
- International subjects (investigators and IRBs should consider local laws and customs in evaluating the majority status of international subjects)

It is sufficient for researchers to use a verbal statement to confirm a child is indeed emancipated. A confirmation of such a claim can be done in a similar way to the verification of individuals who claim to be married or over the age of 18. For example, a researcher, keeping in mind that under North Carolina law a child is not eligible to be emancipated by a court until he or she is 16 years or older, could ask the child his/her age and how long he/she has been emancipated. This age restriction does not apply to married children, who are considered emancipated by virtue of being married regardless of age. A researcher could also simply ask about the process the child went through to get emancipated (i.e., see if the child talks about going to court).

Investigators and IRBs should consult with the Office of University Counsel if there are questions regarding legal issues related to guardianship and/or the age for consent.

28.10 Parental permission

Unless otherwise provided by State law, or unless this requirement is waived by the IRB pursuant to 45 CFR 46.408(c), the permission of the parent or legal guardian is required in order for children to participate in research.

Where research is approved under 45 CFR 46.404 or 46.405 (see SOP 35.3), the IRB may find that permission of one parent is considered sufficient for the child's participation.

Where research is approved under 45 CFR 46.406 or 46.407 (See SOP 35.3), permission is to be obtained from both parents 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.

Per 45 CFR 46.408(c), in addition to the normal waiver requirements, the IRB may waive the parental permission requirement if the research is not FDA-regulated *and* it determines that a research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. This waiver might apply to studies involving neglected or abused children, or older adolescents presenting in medical situations wherein a parental consent requirement might deter the child from seeking needed care (e.g., seeking care at a sexually transmitted disease clinic). If parental permission is waived, the IRB must be sure that an appropriate mechanism for protecting the child is substituted. The choice of an appropriate mechanism would depend on the nature and purpose of activities in the protocol, the risk and benefit to the subject, and their age, maturity, status, and condition.

28.10.1 Durability of Parental Permission

Generally, if a subject whose participation was provided through parental permission reaches the age of majority or becomes legally emancipated during the period of his or her active study participation involving contact with study investigators, the informed consent of that subject should be required for continued participation in the study. The IRB may waive this requirement for informed consent if the criteria for such a waiver are met. See SOPs 28.3, 28.4 and 28.7 above.

28.11 Surrogate consent for subjects who are decisionally impaired

28.11.1 What is Decisional Impairment?

In the absence of a specific legal or medical finding to the contrary, the individual subject must be presumed to have decision making power for himself/herself and must give consent, informed to the best ability of the research team. If there is any doubt as to the subject's capacity to consent, the investigator and the IRB should consider the need for independent assessment of capacity (e.g., psychiatric consult). If the subject does not have decisional capacity and the IRB has approved enrollment via surrogate consent, consent should be obtained from the highest available surrogate representative as described below.

There is an important distinction between the legal meaning of the term "incompetent" and our broader use of the term "decisionally impaired."

Decisionally impaired persons are those who, due to a psychiatric, organic, developmental or other disorder or situation that affects cognitive or emotional functions, are unable to exercise independent decision making. "Incompetence" is a finding of a court of law that results in the appointment of a legally authorized representative for the individual judged incompetent by the court (see "court appointed guardian" below). Persons who have been judged "incompetent" in a court of law are only a subset of the larger group of persons who may be decisionally impaired.

Decisional impairment in a human research subject may be determined by a court finding of incompetence, by a physician's determination, or by a reasonable determination by the investigator or an independent consultant that the surrounding circumstances indicate that the individual is not able to exercise competent judgment about her/his personal risks and benefits in research participation. If a determination of decisional impairment is not confirmed by a court or physician, but only suspected, then consent should be obtained from both the subject and the appropriate representative.

28.11.2 Who can act as a legally authorized representative (LAR) for a decisionally impaired research subject in North Carolina?

As is the case for most states, North Carolina does not have State legal statutes that specifically address research enrollment. In accordance with federal regulations and guidance from the OHRP, UNC-Chapel Hill has established that the informed consent laws applicable to clinical care in North Carolina (North Carolina General Statute 90-21.13) will be followed to determine who would be considered an acceptable LAR for purposes of providing surrogate consent for decisionally impaired subjects in studies conducted in North Carolina. Although the statute is specific to medical care, it may reasonably be applied to research participation as well.

In the case of an adult subject who lacks the capacity to consent, the LAR of the subject will be determined by taking the following individuals in this order of priority:

(1) **Court-appointed legal guardian** (except to the extent any appointed health care agent has authority, unless the health care agent's authority has been suspended by a court order) is a court appointed guardian granted "general" guardianship or "guardian of the person" may provide surrogate consent for all activities of the individual; therefore, this guardian may provide surrogate consent for research participation of the individual.

(2) A **health care power of attorney (HCPOA)** is a health care agent pursuant to the execution of health care power of attorney document. A HCPOA document (to the extent of authority granted) grants the agent power to make health care decisions for the individual following a physician's determination that the individual lacks adequate capacity to make her/his own health care decisions. Therefore, if such a physician determination has been made, the agent under an HCPOA may provide surrogate consent for research participation, to the extent this does not contradict the written HCPOA.

(3) **A durable general power of attorney** grants the agent whatever authority is specified in the power of attorney document and is referred to as an attorney-in fact. Where the power of attorney includes a specific provision stating that it shall survive any period of incapacity or mental incompetence of the principal it is considered a “durable” power of attorney, and the person holding power of attorney may provide surrogate consent for research participation unless the research participation includes an activity expressly excluded from the power of attorney. NOTE that a general power of attorney is only valid when registered with the register of deeds in either the county named in the power of attorney or the county in which the principal resides. Before relying on the decision of a person holding a general power of attorney, investigators should require proof that the power of attorney has been registered and should examine the document to ensure that it expressly survives any period of incapacity or mental incompetence of the principal. For assistance with these determinations, please contact the Office of University Counsel.

Where there is both a valid HCPOA and a valid general power of attorney, the person holding the HCPOA has priority over the person holding the general power of attorney in making decisions regarding participation in human subjects research.

(4) In the event that there is neither a court appointed guardian nor an agent under a durable general power of attorney or HCPOA, surrogate consent for research may be given, as long as there is no evidence to the contrary, by the **other individuals listed below**, in order of priority. When surrogate consent will be sought from one of these individuals, in the absence of a legal designation, their authority would be no broader (and may be more limited) than that of a duly appointed health care agent:

(4a) The subject’s spouse;

(4b) A majority of the subject’s reasonably available parents and adult children;

(4c) A majority of the subject’s reasonably available adult siblings; or

(4d) Another individual with an established relationship with the subject who is acting in good faith on behalf of the subject and can reliably convey the subject’s wishes.

To determine the authorized representative, refer to UNC Health Care System Policy ADMIN 0019, Authorized Representatives of Patients. If there is any doubt as to which individual is the legally appropriate authorized representative for the subject, the Office of University Counsel must be contacted.

NOTE: In the case of designations (1), (2) or (3) above, the investigator should obtain a copy of the court order, HCPOA, or durable power of attorney and should maintain the copy with the research records as documentation of the authority of the surrogate decision maker.

Beyond the categories described above, others may not give surrogate consent for research enrollment. Institutional custodians or caretakers are not legally authorized representatives in the absence of a specific court appointment granting them guardianship (see above).

ADDITIONAL NOTES:

- While the presumption is that primary consent under these circumstances (i.e., decisional impairment) will be obtained from the LAR, there may be occasions when it is possible to seek the assent of the subjects, in addition to consent of the LAR. The IRB will determine whether assent of the participants is a requirement, and if so, whether the plan for assent is adequate.
- IRBs and investigators should seek guidance from the Office of University Counsel if there are questions about legal authorization for surrogate consent in specific situations.
- See SOP 32.5 for more information on IRB review of research involving decisionally impaired persons in research, and limits on this participation. For emergency research scenarios, see SOP 20.0, Emergency Use of a Test Article and SOP 21.0 Exceptions from Informed Consent Requirements for Emergency Research.”
- The foregoing applies to studies in North Carolina. For studies that will be conducted in other states or countries, the investigator will be expected to determine local requirements for legally authorized representatives in consultation with the Office of University Counsel.

28.12 Obtaining consent from non-English speaking subjects

Researchers should take great care when they obtain informed consent from individuals who do not speak English or whose understanding of the language is limited. Researchers should be fluent in the subject’s language or an interpreter should be available during the consent process and throughout the subject’s participation as needed. Consent forms should be prepared in the language understandable to potential subjects. For more information, see SOP 28.13 below.

When performing research using non-English speaking subjects, the use of short form consent documents should **only** be used when unexpected circumstances arise and there is not sufficient time to prepare a full consent form translation. The short form should not be used as a convenient way to circumvent translation of the full consent form. See SOP 28.6 for more information.

While the use of non-English speaking subjects presents a unique set of challenges for the researcher, care must be taken not to exclude non-English speaking subjects from research that may have potential benefits.

28.13 Translation and informed consent

Attention should be paid to both oral interpretation and written translation in the informed consent process.

28.13.1 Oral interpretation

Oral interpretation should be performed by a qualified individual who is not a family member of the prospective subject. The individual performing the interpretation should be available for ongoing communication between subjects and investigators.

28.13.2 Written translation

Written translation of informed consent documents should be performed by a qualified individual. Though there is no standard definition of what constitutes a “qualified individual,” the investigator should demonstrate due diligence in obtaining an adequate translation of the informed consent documents from an individual whose qualifications would appear adequate to a reasonable person. Back translations to English may be one method for validating the accuracy of the translation; however, back translations are not always sensitive to dialect and idiom.

28.14 Consent for use of stored samples and genetic testing

In general, all anticipated uses of collected samples of human tissues, body fluids, or biological products should be carefully delineated in the *Procedures* section of the consent form. Issues to be addressed might include the specific information to be obtained, whether the information may be of value to the subject, whether and how that information will be disclosed or made available to the human subject and whether genetic counseling will be available at the subject’s option.

28.14.1 If specimens are to be collected and stored for as yet unspecified purposes (genetic testing or otherwise), this should be addressed in the *Procedures* section of the consent form or in an addendum. The IRB will provide templates addressing these issues. Whether these templates must be included as an addendum to the consent form depends on the study. Generally, in cases where the primary purpose of the study is to store specimens, then the addendum is unnecessary. The addendum is required when specimen storage is adjunct to the main purpose of the study.

The consent form and process for maintaining human specimens in a repository for future research uses must inform the subjects explicitly about the unspecified possible future use of the specimens and related personal information. The consent process should consider the following:

- The sample will be stored and possibly used in future research studies.
- A description of any personal information about the specimen source that will be maintained (this may or may not include identifiers).
- If no personal identifiers will be used for labeling the stored samples, i.e., if it is impossible for the sample to be linked with the subject, the consent form should so state.
- If personal identifiers are to be used that will allow future matching of the subject to the collected sample, the consent form should

describe how they will be used, how privacy and confidentiality will be protected, and whether and under what circumstances identifying information would be disclosed.

- Future research using the samples will be reviewed by the IRB prior to additional use of the samples
- Whether and how researchers may contact individuals whose specimens are in the repository
- A statement about any potential commercialization and that there are no plans for subjects to share in financial proceeds that may accrue from products derived from the specimens.
- Whether, how, and under what circumstance results from research studies using the specimens would be communicated to the subjects and, where relevant, to their family members).
- If specimens are individually identifiable, how the specimens and associated data may be withdrawn from the repository. If the specimens are not individually identifiable, a statement that they may not be withdrawn for that reason. Specimens that have already been used and the data derived from their use cannot generally be withdrawn.

28.15 Consent for inclusion in research registry

A research registry is a database of potential research subjects who have signaled their willingness to participate in research studies. Subjects must consent to inclusion in the registry. However, researchers may use a staged consent process in which preliminary consent is granted by subjects when they are included in the registry and additional consent is obtained when those subjects participate in a study.

28.16 Disposition of consent documents

As noted above, participants or their Legally Authorized Representative (LAR) must sign and date the consent form prior to participating in the study, unless this documentation is waived by the IRB. A copy of the signed consent form (photocopy or duplicate signed original) shall be given to the person signing the form. An original signed consent form should be retained in the investigator's files.

28.17 Stamped copies of consent forms

All consent forms following the standard template will receive the IRB approval stamp that includes the current approval period. The IRB may require that copies signed by participants include a stamp of approval.

28.18 Research consent forms in health care records

An informed consent document for research participation is not a health care document and ordinarily would not be included in a health care record. Similarly, other forms of information about research interventions that are not health care would not ordinarily be included in an individual's health care record.

However, some clinical research includes health care. Additionally, information about some research interventions, whether or not treatment-related, may be relevant to a health care provider's diagnosis and treatment decisions about the

individual. For example, it may be important for a health care provider not associated with the research study to know that a patient is receiving drugs or interventions as part of a research protocol. In these circumstances it may be appropriate for the consent form to be included in the health care record.

At the time of the review, the IRB, in consultation with the PI, should make a determination as to the appropriateness of including the consent form in the health care record. Conversely, there may be circumstances where it is inappropriate to include the consent form in a subject's health care record, and specific mechanisms should be in place to exclude research information from the health care record (e.g., when research participation is not relevant to ongoing health care but might disclose sensitive personal information such as sexual preferences). If the decision is made to include the consent form in the health care record, then the informed consent and HIPAA authorization for the study should state that this information will be placed in the health care record.

In determining whether research participation records will be placed in the health care record, IRBs and investigators should consider several points. Although protection of the subject's health and safety by providing research participation information to a health care provider is an appropriate concern, there are also other human subjects welfare issues to be considered, particularly privacy and confidentiality. Some human subjects will not want information about their research participation to be shared with their healthcare provider for a variety of reasons including personal privacy or the concern that the information may be transmitted to a health insurer or employer. These are the very privacy and confidentiality concerns that underlie the HIPAA regulations giving patients the right to know what is in their health care record and to control disclosure of their PHI from the health care record.

28.19 Record retention of informed consent forms

As with all protocol related materials, a copy of the approved consent documents (not the signed consent forms themselves) should be retained by the IRB for a minimum of three (3) years following the end of the study. For more information on storage of records, see IRB records requirements.

References:

45 CFR 46.116

45 CFR 46.117

45 CFR 46.404-408

FDA Information Sheet – Guidance for Institutional Review Boards, Clinical Investigations and Sponsors - Off label and Investigational Use of Marketed Drugs, Biological and Medical Devices

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