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Chapter 5 - Informed Consent and Related Issues

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A. The Process of Consent and Assent

Obtaining informed consent is a basic ethical obligation for researchers. The process of consent should ensure that potential subjects are provided with information about the research project that is understandable and permits the subject to make an informed and voluntary decision about whether or not to participate. The amount of information and the manner of presentation is generally related to the complexity and risk involved in the research study. While the initial process is prospective and takes place prior to any research activity, consent should also be an ongoing educational interaction between the investigator and the research subject that continues throughout the study. It is not an exercise in persuasion. If an investigator has a relationship with potential subjects (physician-patient, instructor-student, employer-employee), care should be taken to avoid recruitment methods that may be seen as coercive due to the special relationship between parties.

Except in certain minimal risk studies, the Informed Consent Document is typically signed after the investigator has verbally explained the purpose and procedures involved in the study, answered questions, and otherwise provided information that permits the subject to make a prospective, informed decision. The Informed Consent Document must be signed before any study data collection procedures begin. The Informed Consent Document itself serves as a written source of information for the subject and documents the fact that the process of consent occurred.

Consent is a legal concept. Only legally competent adults can give legally effective informed consent. Minors and those individuals who are not competent to provide consent should be given the opportunity to *assent* to participate in the

research project. *Assent is a knowledgeable agreement to participate in the project.* Adequate provisions should be made for soliciting the independent, non-coerced assent from minors or cognitively impaired persons who are capable of a knowledgeable agreement. In general, the IRB recommends that children age seven and older, and most cognitively impaired adults, be given the opportunity to assent.

In cases where assent is obtained from a minor or cognitively impaired subject, permission must also be obtained from a legally authorized representative.

[NOTE: See [Chapter 8, Section D](#), Vulnerable Populations, for more information about enrolling cognitively impaired subjects in research studies.]

- In studies involving minors, the legally authorized representative is the
 - parent, or
 - court-appointed guardian.
- In studies involving cognitively impaired adults, the legally authorized representative is the
 - designated proxy (such as a Durable Power of Attorney for Health Care),
 - court-appointed guardian,
 - spouse,
 - adult child,
 - parent, or
 - adult sibling.

In studies involving cognitively impaired adults, *permission must be sought from the first existing person in the above list*, even if another relative is more conveniently available. For example, if a married person does not have a designated proxy or court-appointed guardian, the investigator must obtain permission from the spouse, even if an adult child or parent is present and available. Similarly, if a divorced person has adult children and does not have a designated proxy or court-appointed guardian, then the investigator must obtain permission from an adult child, even if a parent is present and available.

If the person from whom assent is sought refuses, the person should not be enrolled, even if the parent or legally authorized representative gives permission. (The IRB may make an exception to this guideline in studies of children with life-threatening illnesses who are eligible for research treatment protocols.)

Alternatively, if the person from whom assent is sought agrees to participate, the person may not be enrolled if the parent or legally authorized representative does not give permission. In rare circumstances, depending on the nature of the study and the age and circumstances of the minor, the IRB may waive the requirement for parental or legally authorized representative permission.

B. Standard Informed Consent Document

The purpose of an Informed Consent Document is to provide subjects with a written source of information for future reference and to document the fact that the process of informed consent occurred prior to the subject's participation. The form generally serves as a basis for the initial presentation of the study to the potential subject. Typically, informed consent is documented by using the written Informed Consent Document approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy of the Informed Consent Document should be given to the subject. Unless the investigator has requested a waiver of documentation of consent, the subject's signature on an Informed Consent Document is required prior to beginning any study procedures.

Although the research study and Consent Document must be reviewed and approved by the IRB at least once per year, subjects enrolled in the study generally sign the Informed Consent Document only once, when initially enrolled. The consent process, however, should be an ongoing interaction between the investigator and the research subject. The exception to this is when the IRB or study sponsor requires subjects to sign a revised Consent Document due to a modification in the protocol or adding new information that may affect the subject's willingness to participate further in the study.

The Informed Consent Document template on the Human Subjects Office web site contains examples of text for preparing an Informed Consent Document. General instructions appear at the beginning of the template. At the end of the template, there is an Appendix containing suggested language for special situations. By following the template, the investigator ensures that the basic and additional elements of consent as required by the federal regulations are included.

The IRB expects all persons involved in the informed consent process to be individually listed as members of the research team at the beginning of the Informed Consent Document.

The basic elements of informed consent, as described in [45 CFR 46.116](#), are as follows:

- 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 which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- For research involving more than minimal risk, an explanation as to whether any compensation 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.
- 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.
- 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.

The federal regulations stipulate that additional elements of informed consent should be provided when appropriate. The additional elements include:

- 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.

Some common problems with the Informed Consent Document include the use of jargon, technical, or scientific terms that a lay person would not understand, and units of measure given in metric rather than the lay equivalents. Ordinary language should replace technical terms (e.g., upper extremities are better referred to as arms, hematoma as a bruise, venipuncture as taking blood from your arm with a needle, and so forth. But perhaps the most common problem with Informed Consent Documents is that they are written at a reading level several grades higher than the average subject would understand. Informed Consent Documents should be written at a reading level that potential subjects would understand. For most projects, an eighth grade reading level is suggested. Most word processing programs can determine a document's reading level.

Tips for writing a "user-friendly" Informed Consent Document

- Write the Consent as though you were speaking to the person who will read it, using you and your, we and our, rather than third person.
- Use language that could be understood by a junior high student.
- Put technical jargon into lay terms (e.g., describe the amount of a blood draw in teaspoons rather than milliliters; use cancer rather than carcinoma). See Related Links, [Federal Regulations and Guidance Material](#), on the HSO website, for links to glossaries of medical terminology in lay language.
- Clearly define complicated terms (e.g., randomization means the study treatment you'll receive will be decided by chance, like flipping a coin).
- Don't give a lot of technical information that participants don't need to know (e.g., complicated methods of determining drug doses, exhaustive lists of specific lab tests).
- Use bulleted lists rather than long sentences.
- Use headings and subheadings as appropriate with logical and consistent formatting.
- Use tables and charts to explain when/where each procedure will take place.
- Use pictures and diagrams to help describe devices.
- Number each page of the document.
- Use hard page breaks to eliminate widow and orphan lines of text.
- Use a font with a serif (e.g., Times New Roman easier to read).
- Use consistent and reasonable font size (e.g., 12 point).
- Do not right justify the text.

Teenage Subjects How to Handle Wording on the Consent Document

If you plan to recruit teenage subjects, and the Informed Consent Document is written at an appropriate reading level, both the teenager and the parent/guardian may sign the Informed Consent. The teen's signature on the Informed Consent Document indicates knowledgeable agreement to participate (assent), and the parent/guardian's signature indicates legal consent. Rather than using you/your child, use the word you throughout, and insert the following statements at the very beginning of the Consent:

- If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word you in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate.
- If you are a teenager reading this document because you are being invited to be in this study, the word you in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

Signature Lines

In general, the Informed Consent Document must include signature lines for the subject, the person who obtained consent, and, for studies involving minors or cognitively impaired individuals, a parent, guardian, or legally authorized representative.

In some types of studies (e.g., mail-out surveys), the investigator may request a waiver of the subjects signature (waiver of documentation of consent see [Chapter 5.G.](#) below) when submitting the New Project Application Form. In such cases, the conclusion of the Informed Consent Document (which could be formatted as a letter to the subject) should inform the subject that returning the survey will be considered evidence of consent. When there is no verbal communication with potential subjects (e.g., mail-out surveys), the signature of the person who obtained consent may also be waived. Note: the HIPAA Privacy Rule does not permit a waiver of documentation of consent/authorization if the study data include protected health information.

An auditor/witness signature line is needed only if specifically required by the IRB or the funding agency/company.

C. Related Documents

1. VAMC Template

The Veterans Affairs Medical Center requires that the standard Informed Consent Document be copied onto its own special form. The form and instructions for its use is on the Forms/Templates page of the Human Subjects Office web site.

2. Assent Document

The Assent Document is used when the investigator recruits subjects who, by age or circumstance, are not able to give legally effective informed consent. When legally effective informed consent cannot be obtained, the investigator should obtain the "assent" of the minor or cognitively impaired subject. This form documents the minor's or cognitively impaired subject's knowledgeable agreement, or assent, to participate in a research project. The investigator should respect the decision of a minor or cognitively impaired subject *not* to participate, even when the parent or legally authorized representative gives permission, unless specifically instructed otherwise by the IRB.

For studies involving children, the IRB recommends that this form be used with children who are in the 7-12 age range, but it may also be used when teenagers are being recruited to enhance their comprehension if the study involves complicated procedures.

When using an Assent form, the child or cognitively impaired adult should sign the Assent to indicate knowledgeable agreement (assent) to participate. In addition, the parent/guardian or legally authorized representative should sign the full Informed Consent Document to document his/her permission for the minor or cognitively impaired adult to participate.

A template is available on the Forms/Templates page of the Human Subjects Office web site.

3. Record of Consent

When a research project involves UIHC patients, it is the UIHC policy that a signed copy of the standard Informed Consent Document must be placed in the subjects medical record chart. However, there are circumstances when the investigator may wish to place a more confidential document in the patients medical record. In such cases, a Record of Consent may be used. The Record of Consent does not contain the project title or a description of the study. The only identifying information is the IRB ID number.

Using a Record of Consent form means that the subject would sign two research Consent forms. First, the subject would sign the regular Informed Consent Document, and the investigator would keep that copy in his/her research records. The subject would also sign the Record of Consent, and the investigator would place that form in the subjects medical record chart.

A Record of Consent may be used (*in addition to* the regular Informed Consent Document) when:

- additional confidentiality is desired (e.g., genetic studies, studies of illicit drug use or illegal behaviors, some psychiatric research), or
- the information contained in the regular Informed Consent Document is not relevant to the subjects care (e.g., single blood draw for a lab study).

The investigator may propose using this form when submitting an application to the IRB. For certain studies, the IRB might require the use of a Record of Consent as a condition of approval.

A template is available on the Forms/Templates page of the Human Subjects Office web site.

4. NIH Certificate of Confidentiality

(from NIH Office of Extramural Research web site)

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Identifying information is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject.

By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring privacy to subjects.

Certificates can be used for biomedical, behavioral, clinical or other types of research that is sensitive. Sensitive means that disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

Examples of sensitive research activities include but are not limited to the following:

- * Collecting genetic information;
- * Collecting information on psychological well-being of subjects;
- * Collecting information on subjects' sexual attitudes, preferences or practices;
- * Collecting data on substance abuse or other illegal risk behaviors;
- * Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).

A Certificate of Confidentiality protects personally identifiable information about subjects in the research project while the Certificate is in effect. Generally, Certificates are effective on the date of issuance or upon commencement of the research project if that occurs after the date of issuance. The expiration date should correspond to the completion of the study. The Certificate will state the date upon which it becomes effective and the date upon which it expires. A Certificate of Confidentiality protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect. An extension of coverage must be requested if the research extends beyond the expiration date of the original Certificate. However, the protection afforded by the Certificate is permanent. All personally identifiable information maintained about participants in the project while the Certificate is in effect is protected in perpetuity.

While Certificates protect against involuntary disclosure, investigators should note that research subjects might voluntarily disclose their research data or information. Subjects may disclose information to physicians or other third parties. They may also authorize in writing the investigator to release the information to insurers, employers, or other third parties. In such cases, researchers may not use the Certificate to refuse disclosure. Moreover, researchers are not prevented from the voluntary disclosure of matters such as child abuse, reportable communicable diseases, or subject's threatened violence to self or others. However, if the researcher intends to make any voluntary disclosures, the consent form must specify such disclosure.

In the Informed Consent Document, investigators should tell research subjects that a Certificate is in effect. Subjects should be given a fair and clear explanation of the protection that it affords, including the limitations and exceptions noted above. The University of Iowa Informed Consent Document template contains suggested language to describe the protection afforded by a Certificate of Confidentiality.

The investigator may choose to apply for a Certificate of Confidentiality on his or her own, or the IRB may require that an investigator obtain a Certificate prior to conducting the research. Investigators who intend to apply for a Certificate of Confidentiality should contact the Human Subjects Office regarding procedural steps for IRB approval and communicating with NIH. Complete information is available on the [NIH Office of Extramural Research](#) web site.

UI Procedures

Because NIH requires that the investigator submit an IRB-approved Consent Document that includes a description of the Certificate of Confidentiality, the investigator must wait until after receiving IRB approval before applying for the Certificate. This means that the investigator will have in hand a stamped, approved Informed Consent Document that describes the special protections of a Certificate, but will not yet have the Certificate itself. Therefore, in order to ensure that the Consent is not used before obtaining the Certificate, the HSO places a "watermark" across each page of the stamped Consent that indicates it may not to be used to enroll human subjects.

The PI should apply for a Certificate following the instructions on the NIH web site (http://grants.nih.gov/grants/policy/coc/appl_extramural.htm). The application letter must be signed by a University of Iowa institutional official. The PI should bring the application letter to the Human Subjects Office and the HSO will obtain the institutional official's signature and return the signed letter to the PI. When the PI receives the Certificate, it should be sent to the HSO with a note indicating the IRB ID#, and the HSO will then send the PI the stamped Informed Consent Document with the "watermark" removed.

D. Safeguarding Confidentiality

An issue of primary importance is the protection of confidentiality, especially in a wide range of social and behavioral projects. These projects include personality inventories, interviews, questionnaires, or the use of observation, photographs and film, taped records, or stored data.

The investigator must have sound plans to protect the subject's identity as well as the confidentiality of the research records. Care should be taken to explain the mechanisms that have been devised, for example, the use of numbering or code systems or safely locked files in private offices. Furthermore, the investigator should describe who has access to the data and under what circumstances a code system may be broken. Without appropriate safeguards, problems may arise from long-term retention of records. In special circumstances requiring additional safeguards to prevent potential criminal prosecution of the participating human subject, the IRB may require the destruction of all data that can identify the subjects.

A special situation arises for video or taped data and photographs since these media provide additional potential means for subject identification. Investigators must secure subject consent explicitly mentioning these practices. They should also explain plans for final disposition or destruction of such records.

E. Recruitment and Subject Compensation Issues

1. Recruitment

Recruitment materials, including brochures, flyers, advertisements, audio tapes, video tapes, and letters to potential subjects, must not contain coercive language or incentives. The information provided should be an accurate presentation of the research study purpose and/or procedures. For example, if the study involves comparing an investigational drug to a placebo, the advertisement should not mention the study drug only. Rather, it should indicate that some subjects in the study will receive a placebo, or describe the purpose of the study as comparing the investigational drug to a placebo.

Any material aimed at recruiting potential subjects into a study (including audio or video tapes) must be reviewed and approved by the IRB prior to being used.

Suggested guidelines for an advertisement or recruitment letter appear below:

* Include the purpose of the project and/or briefly state what is expected of the subject. Include the time commitment required of the subject.

* Include the investigator's University department affiliation and where the research will take place.

- * List a contact name and phone number.
- * Do not include the name of commercial sponsors or products.
- * Avoid phrases such as "help needed" or "subjects wanted." The recommended wording is "you are invited" or "participants invited."
- * If participants will be paid for their time/effort, it is recommended that the wording "Compensation Available" be used, rather than specifying a specific amount. Compensation should not be excessive to the nature of the project. If the investigator wishes to include a specific amount of compensation in an ad, the Application Form should include the investigator's justification as to why this is needed.

Sample advertisement acceptable to the IRB:

ALLERGY STUDY: Interested persons are invited to participate in an allergy study being conducted by Dr. Mary Brown at the University of Iowa, Department of Internal Medicine. Study involves 6 visits over 3 months, and having blood drawn. Compensation available. If you are at least 18, have seasonal allergies, and would like more information, contact Sam Smith at 335-1111.

2. Subject Compensation

Payment for participation in research may not be offered to the subject as a means of coercive persuasion. Rather, it should be a form of recognition for the investment of the subject's time, loss of wages, or other inconvenience incurred. Accordingly, compensation may not be withheld contingent on the subject's completion of the study. In most cases involving continued participation, compensation should be given on a reasonable prorated basis to avoid the impression that the investigator is coercing the subject to continue in a study or is punishing the subject for non-compliance.

Information regarding how to process payment for research subjects is posted on The University of Iowa Accounting Services website: <http://www.uiowa.edu/~fusas/>.

F. Non-English Speaking Subjects

If an investigator uses non-English-speaking subjects, the protocol must reflect the methods for assuring full understanding, possibly with the assistance of an interpreter or by using translated Informed Consenting Document(s). When the investigator anticipates enrolling non-English speaking subjects, the IRB reviews and approves a translated version of the Informed Consent Document. The credentials of the person who did the translation must be provided to the IRB.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "[short form](#)" written consent document, in a language the subject understands, should be used to document that the elements of informed consent were presented orally. The short form states that the elements of informed consent required by the regulations have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there must be a witness to the oral presentation. Also, the IRB must approve a written summary of what is to be said to the subject (if the standard Informed Consent Document is presented orally, this requirement has been met). Only the short form itself must be signed by the subject or the representative. However, the witness must sign both the short form and a copy of the full Informed Consent Document, and the investigator who obtains consent must sign the full Informed Consent Document. A copy of the full Informed Consent Document must be given to the subject or the representative in addition to a copy of the short form.

G. Waivers

1. Waiver of Documentation of Consent

In some situations, the IRB may waive the requirement for obtaining a signed Informed Consent Document ([45 CFR 46.117\(c\)](#)). The regulations state that a signed consent form may be waived if the IRB determines 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; or
- * the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Examples of types of studies that fall into the first category are survey or interview studies that contain highly sensitive (e.g., criminal behavior, sexual behavior) questions.

Studies that fall into the second category are mail out surveys about topics that could not reasonably damage a participant's reputation or employability or be otherwise stigmatizing.

Waiver of documentation of consent may mean that no written document is provided to the subject at all, for example, in a random-dial telephone survey study. In this type of study, the telephone interview would begin with a script that includes all of the required elements of consent, but the study subjects would receive no written information about the study, either before or after the interview. The telephone script containing the elements of consent must be included in the New Project Application Form.

On the other hand, the waiver of documentation of consent may mean only that the subject's signature does not have to be obtained. The regulations stipulate that the IRB chair may still require that the investigator provide the subject with a written statement about the research when granting a waiver of documentation. For example, in a mailed-out survey study, the chair may determine that it is reasonable for the investigator to provide the subjects with a cover letter containing all of the basic elements of consent. The letter would simply conclude with a statement that returning the survey or questionnaire would be considered agreement to participate.

2. Waiver of Elements of Consent

Some research projects would not be possible if informed consent from participants were required. The IRB may consider waiving the requirement for some or all of the elements of informed consent ([45 CFR 46.116\(d\)](#)). The regulations state that informed consent may be waived in full or in part if the IRB determines that:

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

Examples of types of studies in which all of the elements of consent have been waived include retrospective chart reviews, or studies of existing pathology specimens (all specimens to be studied have already been collected and are "on the shelf" at the time of the IRB application). Presuming that the study can be classified as minimal risk and that adequate provisions for protecting the confidentiality of the data are in place, the IRB chairs generally find that obtaining consent is impracticable (not possible).

Examples of types of studies in which some of the elements of consent have been waived include certain types of ethnographic research, and studies that require deception. For example, in a minimal risk study involving playing a computer game to test subjects' responses to differential pay-offs or reinforcements, the investigator might indicate in the Informed Consent Document that the purpose of the study is to test reaction time. This deception may be necessary because the study would be compromised if subjects were told the true purpose. In this scenario, one of the basic elements of consent -- the purpose of the study -- could be waived by the IRB chair, and not included in the Informed Consent Document.

If the investigator seeks a waiver of any or all of the elements of consent, the New Project Application Form should describe the reasons for the request, paying particular attention to why the research project would be "impracticable." The term "impracticable" means more than simple inconvenience - it means that the research could not be conducted without the waiver.

Chapter 9 - Special Topics

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A. Chart / Record Reviews

A human subject is defined, in part, as a living individual about whom an investigator conducting research obtains identifiable private information. Therefore, medical chart or other kinds of record review research (e.g., student records) require IRB review and approval. The IRB chair may authorize a waiver of informed consent for chart/record review research studies if the study is minimal risk, the rights and welfare of the subjects are not adversely affected, the research could not practicably be carried out without the waiver, and, when appropriate, subjects are provided with pertinent information after participation.

Generally, a waiver of consent is granted when all of the chart/record information that will be used in the research study exists in the original records *prior to* the date of the IRB application -- such studies are considered retrospective chart/record reviews. However, if some or all of the information that will be used in the research will be taken from charts/records dated some time in the future (i.e., *after* the date of the IRB application), then consent from some or all subjects may be required. In order to assist the IRB in making the determination for waiver of consent, the investigator should provide the inclusive dates of chart/record information that will be used in the study.

In addition to describing the purpose or hypothesis being studied, and the types of analyses that will be done, the investigator should provide the IRB a list of specific variables that will be used from the original source. This could be done in the application itself, or by including the data collection forms that will be used for compiling the chart/record data.

If the research study involves gathering data from the UIHC medical record, the UIHC Joint Office for Compliance requires that a "Request for Information" form be completed and signed. The IRB ID number and date of IRB approval for the project in which the data will be used must be included. The UIHC Medical Record Data Request form is available on the [IRB-01 Forms/Templates](#) page.

ALSO look at: <http://research.uiowa.edu/hso/index.php?get=forms01>

K. Surveys, Questionnaires, and Interview Studies

Not all survey, questionnaire, or interview research is minimal risk. For example, a survey or interview that asks questions about sensitive topics (e.g., childhood abuse, sexual functioning) likely to cause emotional stress or discomfort may require full IRB review.

Some survey research may be classified as exempt from the regulations if the information obtained is recorded in a way that the subject cannot be identified (either directly or through a code numbers or link); in other words, if the research data are anonymous. The term anonymous is sometimes confused with the term confidential. In human subjects research, anonymous means that at no time during the data collection could someone determine who provided the information. If a link existed at any time, even if the link is subsequently destroyed, the IRB cannot consider the information anonymous.

A survey or interview study may also be considered exempt from the regulations even when the data are not anonymous if the information being gathered could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

The most common classification for survey, questionnaire, or interview research is expedited approval. If the study is not anonymous and contains information that, if known, could be damaging as described above, but it does not rise to the level of more than minimal risk, it may be given expedited approval. Although the New Project application gives the investigator the opportunity to indicate a classification, the chairs make the final determination as to the classification of exempt or expedited.

For minimal risk mail-out or web-based surveys or questionnaires, it may be appropriate to request that the chair waive the requirement for the subject's signature on an Informed Consent Document. When the subject's signature requirement is waived, generally the investigator provides all of the required elements of consent in a cover letter, with a statement that returning the survey or questionnaire will be considered voluntary agreement to participate. For additional information on waiver of signature, see Chapter 5.