Tulane University
Human Research Protections Office
Clinical Coordinators Seminar
6/23/09
Informed Consent Process

Human Research Protections Office
Clinical Coordinators Seminar

Writing Informed Consent Documents:

- Informed Consent Document is an important part of the Informed Consent Process
- The only part of the informed consent process that is overseen by the IRB committee/Federal Guidelines
- Although often viewed as such, it should not be constructed as a "legal document"
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Requirements for Informed Consent Documents:
Federal Requirements (45 CFR 46.116)
- 8 required elements to informed consent
- 6 additional required elements, if applicable
- Available at the OHRP website:
  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116

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8 Federal Requirements for Informed Consent Document
(45 CFR 46.116):

(1)
- State the study involves research
- Explain the purpose of the study
- Tell the subject how long study will last
- A description of the procedures to be followed, including invasive procedures
- Identify any procedures that are experimental

(2)
- Describe any "reasonably foreseeable risks" or discomforts
8 Federal Requirements for Informed Consent Document (45 CFR 46.116):

(3) Describe any benefits to participants

(4) Describe any alternative treatments or procedures and potential risks/benefits

(5) Describe procedures for maintaining confidentiality

(6) Explain if any compensation or medical treatment is available for injury

(7) Who to contact in event of research related injury
   Who to contact for answers to questions about the research or their rights

(8) Tell subject that taking part is voluntary and refusal to take part will involve no penalty or loss of benefits
   Tell participant they may stop taking part at any time without penalty or loss of benefits
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**Additional Federal Requirements (If Applicable)
(45 CFR 46.116):**

(1) Treatment/procedure may involve risks to subject (or embryo) that is currently unforeseen

(2) Circumstances under which participation may be terminated by investigator without consent

(3) Any additional costs to the subject for participating

(4) Consequences of decision to withdraw and procedures for orderly termination

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**Additional Federal Requirements (If Applicable)
(45 CFR 46.116):**

(5) Statement that significant new findings developed during the course of research which may affect willingness to continue to take part will be provided to subject in a timely manner

(6) Approximate number of participants to be enrolled
   ▪ Total in study
   ▪ Number to be enrolled at Tulane
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Writing an Informed Consent Document
General Tips:

- **Write the Informed Consent Document in the second person**
  ("You are being asked to...", "side effects you may feel...", "your child...")
- **Write in lay terms and keep it simple**
  Language must be written at or below 8th grade level.
  Keep words < 3 syllables and sentences < 10 words.
  Use bulleted lists as opposed to long paragraphs.
- **Avoid exculpatory language**
  ("You must..." or "You have to..." or any language indicating they "waive" any rights)
- **Keep length to as short as possible**
  Longer consents=less comprehension
- **Follow Tulane IRB Templates as much as possible**
Instructions for Completing the Tulane Biomedical IRB Consent Form Template

IMPORTANT - Please review the following as you prepare the consent form:

- **DELETE** this instruction page and all information in [brackets] from the template in the final document. Information in [brackets] is meant only as a guide for researchers in preparation of the document. Unless otherwise noted, through the use of required and suggested statements, the text within each section may be revised to be appropriate for your study. The required and suggested statements are given in quotation marks to make it easier for you to locate where the statements begin and end. Please note that rewording of required language increases the review time of the consent document by the IRB. Please DELETE all quotation marks when incorporating these statements.

- You should select a font that is easy to read such as Times Roman, Arial, or Garamond and use a font size no smaller than 12 point. Make the font color black in the final document. Separate large blocks of text into paragraphs. Text should line up along the margin.

- The consent document must be written using lay language, at an 8th grade reading level (similar to the level used in popular magazines and newspapers) that is appropriate for the participant population and must be written in the second-person tense (e.g., you are invited to participate, you will be asked, etc.). DO NOT use language copied from the protocol or a grant proposal; avoid technical jargon. The form should be written as if the investigator and participant are engaged in conversation.

- The use of bulleted lists and/or tables may be helpful to explain study procedures, timelines, inclusion/exclusion criteria, etc.

- All pages must contain a 1 inch margin on all sides (exclusive of headers and footers) to allow for sufficient white space and space for the IRB validation stamp.

- Consent form pages must be numbered and should follow the following format "page X of X."

- When amending the consent form, include the Version Date and a space for the Approval Date and Sign By Date in the footer.

- When appropriate, write the full name of the study sponsor (e.g. National Institutes of Health, National Institute of Mental Health).

Unless otherwise noted all sections of the consent form (formatted as shown with proper headings) are required. The format of the template should be appropriate for research studies.

If you have questions concerning use of the template or need assistance preparing the consent form, please contact the Tulane HRPO at 504-988-2665 or irbmain@tulane.edu.

*Forms are subject to change. Check for the latest forms through IRBNet.*
Introduction

[Required statement to begin section: “You are invited to participate in a research study to ...” then continue with the following suggested statement: “You are being asked to participate because you are...”]

[For biomedical studies or studies that are more than minimal risk, include the following suggested statement: “This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and to discuss it with your family, friends and doctor. We also encourage you to ask questions now and at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form.”]

Disclosure of Potential Conflict of Interest

[Suggested statement: “The investigator(s) in this study are also healthcare providers. They are interested in the knowledge to be gained from this study and in your well-being. Investigators may obtain salary or other financial support for conducting the research. You are under no obligation to participate in any research study offered to you.”]

OR

[Suggested statement: “The investigator(s) in this study are also healthcare providers. They are interested in the knowledge to be gained from this study, and in your well-being. Tulane Health Sciences Center receives funding from (name of sponsor) to help cover administrative costs such as record keeping, mail and telephone expenses. However, investigators do not receive salary or other financial support from the study sponsors in exchange for conducting this study. You are under no obligation to participate in any research study offered to you.”]

Why is this study being done?

[Suggested statement to begin section: “The purpose of this research study is ...” or “We are conducting this research study to ....”]
[Describe why you are conducting the study. Provide participants with a clear and accurate statement of the scientific purpose and objectives of the research. Use lay terms. DO NOT repeat the study title.]

[Example: Phase 1 study]

Test the safety of [drug/intervention] at different dose levels. We want to find out what effects, good and/or bad, it has on you and your risk of _______ [insert applicable illness, disease, and/or condition].

[Example: Phase 2 study]

Find out what effects, good and/or bad, [drug/intervention] has on you and your risk of _______. [insert applicable illness, disease, and/or condition].

[Example: Phase 3 study]

Compare the effects, good and/or bad, of [drug/intervention] with [currently-used drug/intervention or placebo] on you and your risk of ______. [insert applicable illness, disease, and/or condition] to find out which is better. In this study, you will get either the [drug/intervention] or the [currently-used drug/intervention or placebo]. You will not get both. [Explain in 1-2 sentences. Examples are: “Currently there is no effective way to prevent this type of cancer in people at increased risk,” or, “We do not know which of these two commonly used drugs is better.”]

**What are the study procedures? What will I be asked to do?**

[If appropriate, list tests and procedures and their frequency under the categories below. Include whether the participant will be at home, in the hospital, or in an outpatient setting.]

[Suggested statement to begin section: “If you agree to take part in this study, you will then be asked to . . . ,” or, “There are two parts to the research study. In the first part you will be asked to . . .”]

[Describe the procedures to be used in the study in sequential order. If participants will be screened, describe screening procedures and major inclusion/exclusion criteria. All experimental procedures must be identified as such.]

[If the research involves questionnaires, surveys or interviews, describe the type of questions that will be asked or the topics covered.]

[Describe where the research will be conducted, when the research will be conducted, the duration of the subject’s participation (in total and per session, if applicable), the total number of subjects to be enrolled, and whether or not the participant will be contacted in the future.]

[Describe procedures for audio or videotape, if applicable.]
[Describe procedures to re-contact participants at a later date for any type of follow-up, if applicable]

[If the research involves use of deception or incomplete disclosure, insert the following suggested statement: "Some research requires that the full purpose of the study not be explained before you participate. We will give you a full explanation at the end of the study." Please note: the last sentence can be further customized to say, "We will give you a full explanation as soon as you complete the study."]

[Example]

Before you begin the study ...
You will need to have the following exams, tests or procedures to find out if you can be in the study. These may be a part of regular care for someone at increased risk for _______ [insert applicable illness, disease, and/or condition, or delete if not applicable]. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.
- [List tests and procedures as appropriate. Use bulleted format.]

During the study ...
If the exams, tests and/or procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures.
- [List tests and procedures as appropriate. Use bulleted format.]

These tests and procedures may be part of regular care for someone at increased risk for _______ [insert applicable illness, disease, and/or condition or delete if not applicable]. They may be done more often because you are in this study.
- [List tests and procedures as appropriate. Use bulleted format. Omit this section if no tests or procedures are being done more often than usual.]

You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body.
- [List tests and procedures as appropriate. Use bulleted format. Omit this section if no tests or procedures are being tested in this study or required for safety monitoring.]

[For randomized studies:] You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance.
A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an [equal/one in three/etc.] chance of being placed in any/either group.
If you are in group 1 (often called "Arm A") ... [Explain what will happen for this group.]

If you are in group 2 (often called "Arm B")... [Explain what will happen for this group.]

[For studies with more than two groups, an explanatory paragraph containing the same type of information should be included for each group.]

[NOTE: Specify how subjects will take the study agent (times/day, dosage, and route of administration. List all paperwork (i.e., diaries, questionnaires, etc.) that the participant will be asked to complete. List specimens to be collected, including frequency and amount.]

When I am finished taking [drugs or intervention]...

[Explain the follow-up requirements, tests, procedures, exams, etc. required, including the timing of each.]

[Optional Feature: In addition to the required narrative explanation found in the preceding text, a simplified calendar (study chart) or schema (study plan) may be inserted here. Instructions for reading the calendar or schema should be included. See examples.]

**Study Plan [Example]**

You will receive [drug(s) or intervention] every [insert appropriate number of days or weeks] in this study. The study calendar below shows what will happen to you during the study.

**Study Calendar [Example]**

<table>
<thead>
<tr>
<th>Day</th>
<th>What you do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two days before starting study drug</td>
<td>Get required study blood tests.</td>
</tr>
<tr>
<td>First day of taking study drug</td>
<td>Begin taking ____ once a day. Keep taking ____ until the end of study, unless told to stop by your health care team. Begin study diary.</td>
</tr>
<tr>
<td>Day 8 of the study</td>
<td>Complete Quality of Life Questionnaire.</td>
</tr>
</tbody>
</table>

Approval Date:_____
Sign By Date:_____
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Subject Initials:_____
Day 28

Return to clinic for blood tests. Bring diary and questionnaire. Also bring your pill bottle and any pills that you did not use, or bring the empty pill bottle if you used them all.

Study Flow Chart [Example – note: flowcharts are not needed for all studies]

Another way to find out what will happen to you during the study is to read the study flow chart below. Start reading at the top and read down the list, following the lines and arrows.

Study begins

↓

Agents used in this study

Vitamin A or Vitamin E given daily by mouth for 5 years

↓

Randomize

(You will be in one Group or the other)

Group 1

Vitamin A

Group 2

Vitamin E
What other options are there?

[If this is not a treatment study, this section may not be required. Delete if not appropriate.]

[For research studies that involve TUHSC students, describe alternatives to earning extra credit (e.g. attend lecture, write a research paper, etc.), if applicable.]

What are the risks or inconveniences of the study?

[Inform the participant of any risks (e.g. physical, emotional, and social) as a result of study procedures.
Each procedure should be identified and then the associated risks described. Identify immediate and latent risks and list them in appropriate order, from most likely to least likely to occur. Identify steps taken to minimize risks. Indicate if there may be unforeseen risks. Describe any risks for a fetus or nursing child, if applicable. Inform subjects about availability of referral for follow up or treatment. Include a statement that the subject will be given any new information gained during the course of the study, which might affect her/his willingness to participate.]

[Inform the participant of any inconveniences (e.g. the amount of time required to complete procedures, abstention from food, length of time participants may be required to sit or stand) as a result of study procedures.]

[If there are no known risks, then use the following suggested statement in this section: “We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study. Also consider a breach of confidentiality.”]

[The breach of confidentiality is especially important in studies where genetic testing is done; blood or tissue samples are stored; treatment and/or serologic testing for HIV or hepatitis is performed; registries and medical record reviews.]

What are the benefits of the study?

[Describe any direct benefits to the participant that may be reasonably expected as a result of the research. Describe benefits expected to accrue to the population the participant represents or to society in general (e.g. advancement of knowledge, health benefits to others). DO NOT include payments for participation or other incentives and gifts as a benefit of participation.]

[If participants are not expected to directly benefit, then use the following suggested statement for this section: “You may not directly benefit from this research; however, we hope that your participation in the study may … (describe societal benefits).”]
Will I receive payment for participation?

[If participants will not receive payment, use the following required statement to begin the section: “You will not be paid to be in this study.”]

[Describe any payments (e.g. giftcard) to participants, when participants can expect to receive the payment and the method by which compensation will be given. Include conditions for partial payment or no payment for early termination. If compensation will be paid in stages, list amount for each stage and the total amount pro-rated based on study visits completed.]

[If payments exceed $600 include the following required statement, “Tulane University is required to report payments of $600 or more to the Internal Revenue Service (IRS). This means that if you receive $600 or more from Tulane during the calendar year, your compensation will be reported to the IRS and you will receive an IRS 1099 Form.”]

[For research studies that involve giving extra credit to students, describe the specific amount of extra credit participants can earn for their participation and the method by which this is determined.]

Are there costs to participate?

[If there are no costs to participate in the research, use the following required statement: “There are no costs to you to participate in this study.”]

[If there are costs to participants, as documented in the sponsored agreement, then describe the costs to be paid by the participants. Use the following suggested language: “If your insurer refuses to pay, you will be responsible for paying (include all that apply):

- Costs of the investigative drug, device or material;
- Routine medical costs to conduct the study, including monitoring for side effects and study complications;
- All applicable co-payments and deductibles related to the research item or service;
- Care unrelated to this study.”]

[Describe any costs participants may incur (e.g. parking fees).]

How will my personal information be protected?

[Explain procedures to protect participant’s privacy and the confidentiality of study records and, if applicable, of audio or videotapes. If the study involves use of the internet, e-mail or electronic record keeping, describe procedures to ensure confidentiality of the electronic]
data (e.g., stand-alone servers, firewalls, etc.). State how long study records will be kept, where they will be kept and who will have access to them. Describe how video and audio will be destroyed if no longer needed. If participants are audio or videotaped, describe who will transcribe or view the tapes.]

[If study data is to be released, describe the person(s) or agency to whom information will be furnished, the nature of the information to be furnished, the purpose of the disclosure and whether the participant’s name will be used. This is particularly important for certain vulnerable populations including employees (management access to study data), students.]

[Describe any situations in which confidentiality cannot be guaranteed (such as reporting requirements for child abuse and neglect).]

[SUGGESTED Statement to begin section (be sure to describe procedures specific to your study): “The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location. Research records will be labeled with a unique code. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. Any master key, audio recording, and other data described in this paragraph will be maintained in accordance with the security provisions of this paragraph until destroyed by the researchers. ”]

[Required statement to include last in this section: “You should also know that the Tulane University Human Research Protection Office and the Biomedical Institutional Review Board (IRB) may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.”]

[Required statement for research projects subject to FDA regulations: “To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study device may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the Sponsor or the Sponsor's representatives and may be looked at by the FDA and other regulatory agencies.”]
Tulane University Human Research Protection Office
Biomedical IRB Consent Form for Participation in a Research Study
/Header (Followed by Study Title or Short Title) and Footer on Every Page/

[If a Certificate of Confidentiality is required, describe the extra protection (and limits to such protection) that is afforded. Delete Certificate of Confidentiality section below if no certificate is required. For additional information see http://www.hhs.gov/ohip/humansubjects/guidance/certconf.htm.]

[Example: Certificate of Confidentiality]

To help further protect your privacy, has obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). With this Certificate in Place, the researchers cannot be forced (for example by a court subpoena) to turn over research specimens or information about you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. But, disclosure will be necessary, however, upon request by the DHHS for audit or program, evaluation purposes.

This Certificate does not stop you from volunteering to turn over your research specimens or research information. This means that if someone (like an insurer or an employer) finds out about your research specimens or research information and you say it is OK for them to have it, then researcher here cannot use the Certificate to keep your information private. Your research information would have to be turned over. This means that you still need to be careful to protect your privacy if someone requests your permission to see your study information.

If you tell us that you are being abused or will harm yourself or others, you should understand that the investigator may take steps, including reporting to authorities, to prevent serious harm to you or others.

[Investigators are advised to include language in consent forms for clinical trials that involve genetic testing to inform patients about privacy protections under the Genetic Information Nondiscrimination Act (GINA). OHRP recommends the following suggested text for inclusion in informed consent forms as one example of language regarding GINA’s protections:]

A new federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

Approval Date: ______
Sign By Date: ______
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Subject Initials: ______
Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of Nov. 21, 2009. Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

What happens if I am injured or sick because I took part in the study?

[Only applicable for studies that present greater than minimal risk to participants. Delete if not applicable.]

[Required statement for this section for studies that present greater than minimal risk to participants:

"In the event you become sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If you require medical care for such sickness or injury, your care will be billed to you or to your insurance company in the same manner as your other medical needs are addressed."

OR

"The Tulane University Health Sciences Center and the investigators in this protocol will provide necessary medical treatment for any injury or illness which may arise from your participation in this research. However, such treatment will be on a fee for service basis."]

[If there is no charge to participant for aftercare related to a study-related illness or injury, as documented in the sponsored agreement, use the following required statement: "There are no costs to you to provide necessary medical treatment for any injury or illness which may arise from your participation in this research."]

[If there are charges to participants for aftercare related to a study-related illness or injury, then describe the costs to be paid by the participants. Use the following suggested language: "If your insurer refuses to pay for aftercare related to a study-related illness or injury, you will be responsible for paying costs for aftercare related to a study-related illness or injury, including but not limited to applicable co-payments and deductibles.

The Tulane University Health Sciences Center does not offer any form of compensation for injury or illness arising from participation in this research. If you have any questions, please contact the Office of the Associate General Counsel for Research, Tulane

Approval Date: ______
Sign By Date: ______
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Subject Initials: ____
Can I stop being in the study and what are my rights?

[Required statement to begin section: “You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.”]

[For longitudinal, interventional and/or treatment studies the following statement is required: “You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.”]

[For interviews, focus groups and surveys, it may be appropriate to inform participants that they are not required to answer each question. Use the following suggested statement: “you do not have to answer any question that you do not want to answer.”]

[For certain vulnerable populations it may be necessary to expand upon the “no penalty” statement. For example, if Tulane students will be enrolled include a statement indicating that their “academic standing will not be affected” if they decline to participate. If you are enrolling AIDS patients through a clinic include a statement indicating that the services they receive through the clinic “will not be taken away or changed” if they decline to participate.]

[If applicable, inform participants that they may be withdrawn from the study at any time. Describe conditions for such a withdrawal (e.g. missed appointments, non-adherence to procedures, disruptive behavior during study procedures, adverse reactions).]

Who do I contact if I have questions about the study?

[Include the following required statement on all consent forms and add contact information as appropriate: “Take as much time as you like before you make a decision to participate in this study. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator, (insert name and phone number) or the student researcher (insert name and phone number). If you have any questions concerning your rights as a research participant, you may contact the Tulane University Research Compliance Officer at 504-988-1147 or at researchcompliance@tulane.edu.]
Documentation of Consent:

Use the following required statement and format for this section:

I have read this form and decided that I will participate in the research project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

Subject ____________________________ Date __________

Parent/Legally Authorized Representative (if applicable) ____________________________ Date __________

Person Obtaining Consent ____________________________ Date __________

I am unable to read but this consent document has been read and explained to me by ____________________________ (name of reader). I volunteer to participate in this research.

Subject ____________________________ Date __________

Witness ____________________________ Date __________

Person Obtaining Consent ____________________________ Date __________

Approval Date: ______
Sign By Date: ______
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Instructions for Completing the
Tulane Assent Form Template

IMPORTANT - Please review the following as you prepare the assent form:

- DELETE this instruction page and all information in [brackets] from the template in the final document. This information is meant only as a guide for researchers in preparation of the document. Unless otherwise noted, through the use of required and suggested statements, the text within each section may be revised to be appropriate for your study. The required and suggested statements are given in quotation marks to make it easier for you to locate where the statements begin and end. Please DELETE all quotation marks when incorporating these statements.

- You should select a font that is easy to read such as Times Roman, Arial, or Garamond and use a font size no smaller than 12 point. Make the font color black in the final document. Separate large blocks of text into paragraphs. Text should line up along the margin.

- The assent document must be written using lay language, at an 8th grade reading level (similar to the level used in popular magazines and newspapers) that is appropriate for the participant population and must be written in the second-person tense (e.g., you are invited to participate, you will be asked, etc.). DO NOT use language copied from the protocol or a grant proposal; avoid technical jargon. The form should be written as if the investigator and participant are engaged in conversation.

- The use of bulleted lists and/or tables may be helpful to explain study procedures, timelines, inclusion/exclusion criteria, etc.

- All pages must contain a 1 inch margin on all sides to allow for sufficient white space and space for the IRB validation stamp.

- Assent form pages must be numbered and should follow the following format “page X of X.”

- When amending the assent form, include the Version Date and a space for the Approval Date and Sign By Date in the footer.

- When appropriate, write the full name of the study sponsor (e.g. National Institutes of Health, National Institute of Mental Health).

Unless otherwise noted all sections of the assent form (formatted as shown with proper headings) are required. The format of the template should be appropriate for research studies.

If you have questions concerning use of the template or need assistance preparing the assent form, please contact the Tulane HRPO at 504-988-2665 or irbmain@tulane.edu.

*Forms are subject to change. Check for the latest forms through IRBNet.
Who are we and why are we meeting with you? [Introduction]

Suggested Statement..."We want to tell you about a research study we are doing. A research study is a way to learn information about something. We would like to find out more about [insert purpose of study in simple language]. You are being asked to join the study because [insert name of medical condition or other reasons for inclusion].

What will happen to me in this study? [Description of the study]

[Describe in simple language the procedures (e.g. blood work, questionnaires, medication) step by step that the child/subject will undergo. Also include the number of visits and time frame in words easily understood by a child. Explain the reason for the research. Describe what the child will be expected to do. Describe which part of the study is experimental. Describe all procedures using simple terms and explaining any medical terms.]

Can anything bad happen to me? [Risks or Discomforts of Participating]

Suggested Statement..."Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks. The risks of this study are..."
[Explain any possible risks, discomforts, and/or side effects to the child, using simple terms. If something might be painful, state this within the assent. Explain that the child should inform his/her parents if they are sick or in pain as a result of being in the study.]

Can anything good happen to me? [Benefits of Participating]

[Be very clear as to whether or not they can expect direct benefit. Only describe known benefits to the child. You may include any possible future benefits to others. If there are no known benefits, state so.] Suggested Statement..."We do not know if you will be helped by being in this study. We may learn something that will help other children with [insert name of medical condition or subject matter of study] some day."
Do I have other choices? [Appropriate Alternatives]

[Describe any alternative procedures that might be available to the child other than this study.]

If none, this section can be omitted.

Will anyone know I am in the study? [Confidentiality]

[Explain in simple terms that the child’s participation in the study will be kept secret, but information about him/her will be given to the study sponsor.]

Note: This information may not be applicable in assent forms for very young children.

What happens if I get hurt? [Medical Treatment]

[Describe that the child’s parent’s/legal guardians have been given information on what to do if the child is injured during the study.]

Will I be given anything to take part in this study? [Compensation for Participation]

Suggested Statement...“You will receive ______________ for being in this research study.”

[Payment should be an age appropriate gift card and not cash.]

If no compensation given, this section can be omitted.

Who can I talk to about the study? [Contact Information]

[List people the child can contact if he/she has any questions or problems related to the study.]
Suggested Statement...“You can ask us questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study.

If you have any questions about the study or any problems with the study you can call the Principal Investigator (name of Principal Investigator). You can call him/her at (Principal Investigator’s phone number). You can also call (name) at (phone number).”

Required Statement...”If you have any questions about the study but want to talk to someone who is not part of the study, you can call the Tulane University Human Research Protection Office (HRPO) at (504) 988-2665.”

Approval Date: ______
Sign By Date: ______
Page 2 of 3
Subject Initials: ______
What if I do not want to do this? [Voluntary Information]

[Let the child know that they can stop being in the study at any time without getting in trouble and that their doctor will continue to treat them if treatment is necessary and available.]
Suggested Statement..."You don't have to be in this study if you do not want to. No one will get angry or upset if you don't want to be in this study. Just tell us. And remember, you can change your mind later if you decide you don't want to be in this study anymore."

For Adolescent Girls in the Study [Delete if inappropriate]

If applicable, Suggested Statement..."If the study medicine is taken by a girl who is pregnant (having a baby), it may hurt the baby. If you have had your first menstrual period and have begun to have sex with a boy, it is possible for you to become pregnant. If you have had your first menstrual period, a urine pregnancy test will be done at your first visit to make sure that you are not pregnant. This will not hurt. You will be asked to "pee" in a cup, put it in a tube, and the pregnancy test will be done or the study doctor may take blood from your arm with a needle placed in a vein. There may be a black or blue spot on your arm called a bruise, or bleeding, or infection, at the place where my blood was drawn. But the chances of getting infection are rare.

It is important that you tell your parents or the study doctor if you start having sex while you are in this study. You must use a reliable way to stop yourself from becoming pregnant; this is called "birth control." You can use a condom (also called a "rubber") along with a sperm-killing jelly and birth control pills. The study doctor will answer all of you and your parent's questions about birth control. If you are having sex, but are not sure if the type of sex you are having can cause you to have a baby, please ask the study doctor to explain.

If you don't take a reliable birth control measures, you will not be asked to sign up for this study and asked not to sign this assent form.

You should also tell the study doctor about all medicines that other doctors may have given you to take."
Signature

If you understand this study and you are willing to participate, please sign below:

________________________________________________________________________

Subject Name

________________________________________________________________________

Subject Signature Date

Signature of Investigators or Responsible Individual:

“To the best of my ability, I have explained and discussed the full contents of the study, including all of the information contained in this consent form. All questions of the research subjects and those of his/her parent(s) or legal guardian have been accurately answered.”

________________________________________________________________________

Investigator/Person Obtaining Consent Name

________________________________________________________________________

Signature Date

Approval Date: ______ Sign By Date: ______ Subject Initials: ______

Page 4 of 3
Principal Investigator: Principal Investigator, MD
Study Title: Sample Assent to be in a Research Study about Cancer Treatment for Children ages 7-12
Sponsor: National Cancer Institute

Who are we and why are we meeting with you?

We want to tell you about a research study we are doing. A research study is a way to learn information about something. We would like to find out more about cancer treatments. You are being asked to join the study because we want to find out how well you cancer treatment is working.

What will happen to me in this study?

Two things will happen:

1. A small amount of blood will be drawn. That means it will be taken by a needle in your arm. This will happen every three months for a year.

2. The doctors will do some tests on your tumor/cancer. The part they look at will be removed before the study begins.

Can anything bad happen to me?

The stick from the needle to draw your blood will hurt, but the hurt will go away after a little while. It will not hurt for the doctors to look at the part of your tumor/cancer because it will already be removed.

Can anything good happen to me?

No, this study won’t make you feel better or get well. But, the doctors may learn something that will help other children with cancer some day.

Who can I talk to about the study?

You can ask us questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study.

If you have any questions about the study or any problems with the study you can call the doctor, Principal Investigator, MD. You can call him/her at 555-5555. You can also call Study Coordinator, RN at 555-5555.

If you have any questions about the study but want to talk to someone who is not part of the study, you can call the Tulane University Human Research Protection Office (HRPO) at (504) 988-2665.

Approval Date: ______
Sign By Date: ______
Page 1 of 2

Subject Initials: ______
What if I do not want to do this? [Voluntary Information]

You don’t have to be in this study if you do not want to. No one will get angry or upset if you don’t want to be in this study. Just tell us. And remember, you can change your mind later if you decide you don’t want to be in this study anymore.

Signature

If you understand this study and you are willing to participate, sign below:

______________________________
Subject Name

______________________________       ______________________
Subject Signature                  Date

Signature of Investigators or Responsible Individual:

To the best of my ability, I have explained and discussed the full contents of the study, including all of the information contained in this consent form. All questions of the research subjects and those of his/her parent(s) or legal guardian have been accurately answered.

______________________________
Investigator/Person Obtaining Consent Name

______________________________       ______________________
Signature                  Date

Approval Date: ______
Sign By Date: ______
Page 2 of 2

Subject Initials: ______
Principal Investigator: Principal Investigator, MD; Co-Investigator, MD
Study Title: Sample Assent to be in an HIV-related Research Study for Children ages 13-17
Sponsor: National Health Institute

Who are we and why are we meeting with you?

We want to tell you about a research study we are doing. A research study is a way to learn information about something. We would like to find out more about a medicine called DRUG is safe for treating children with HIV.

You are being asked to join the study because you are infected with HIV (Human Immunodeficiency Virus).

What will happen to me in this study?

1. First, the study doctor will ask you questions about your health. You will have a physical exam and you will give some urine and blood for testing.

2. Then, if you are going to stay in the study, you will get the DRUG. The DRUG medicine will be given through a needle in your arm.

3. During the 9 months of the study, you will need to visit the clinic/hospital at least 19 times for physical exams and blood tests. Each visit will last 1 to 7 hours.

4. You will be given the DRUG 6 times, about once a month.

Can anything bad happen to me?

Sometimes things happen to people in research studies that may hurt them or make them feel bad. It may hurt when a needle is put in your arm to take blood or to give you the DRUG. The doctors will ask you if you want a numbing medicine on your skin to try and make it hurt less.

You should inform your parents if you become sick or are in pain because of the in the study.

Can anything good happen to me?

You may get a little better by being in this study or you may stay healthier for a longer time, but we don't know if that will happen. The doctors don't think that the DRUG will make your HIV infection go away completely.

Will anyone know I am in the study?

If you agree to be in this study, it will be kept secret, but information will be given to the study sponsor.

What happens if I get hurt?

Your parents have been given information on what to do if you are injured during the study.

Approval Date: ______
Sign By Date: ______
Page 1 of 2
Subject Initials: ______
Who can I talk about the study?

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study.

If you have any questions about the study or any problems with the study you can call the Study Doctor, ______________, MD. The study doctor can be called at ___________. If you want, you can call the Study Coordinator, ______________. The Study Coordinator can be called at ___________.

If you have any questions about the study but want to talk to someone who is not part of the study, you can call the Tulane University Human Research Protection Office (HRPO) at (504) 988-2665.

What if I do not want to do this?

If your parents agree, you can be in this study if you want to. You don’t have to be in this study if you do not want to. No one will get angry or upset if you don’t want to be in this study. Just tell us. And remember, you can change your mind later if you decide you don’t want to be in this study anymore.

Signature

If you understand this study and you are willing to participate, sign below:

__________________________________________
Subject Name

__________________________________________    _____________
Subject Signature                      Date

Signature of Investigators or Responsible Individual:

“To the best of my ability, I have explained and discussed the full contents of the study, including all of the information contained in this consent form. All questions of the research subjects and those of his/her parent(s) or legal guardian have been accurately answered.”

__________________________________________
Investigator/Person Obtaining Consent Name

__________________________________________    _____________
Signature                      Date

You will receive a copy of this form.
Tulane University

Human Research Protection Office

Consent Process Checklist

Regulatory References for this Checklist include: 45 CFR 46.116, 45 CFR 46.117, and 21 CFR 50.20. If you have questions or concerns regarding this Checklist, you may contact irbmain@tulane.edu.

General Format/Style Issues:

Is the Consent Form formatted with the proper headers (Study Title, Name of PI, Name of Faculty Advisor (if appropriate) and proper page numbers according to the Templates?

☐ Yes ☐ No ☐ N/A

Is the consent form written in lay language (approximate 8th grade reading level) that will be readily understood by the intended audience?

☐ Yes ☐ No ☐ N/A

Is the consent form written in the second person (e.g. you are invited to participate, you will be assigned, or your child is invited to, etc.) throughout the document?

☐ Yes ☐ No ☐ N/A

Is the consent form legible with plenty of white space, 1 inch margins on all sides, and written in at least a 12 point font?

☐ Yes ☐ No ☐ N/A

Does the consent form contain exculpatory language throughout which the subject or the subject’s representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the research investigator, the sponsor, the institution, or its agents from liability or negligence? If so, this language must be removed.

☐ Yes ☐ No ☐ N/A

Is there a disclosure of a potential conflict of interest?

☐ Yes ☐ No ☐ N/A

Invitation to Participate:

Is the potential subject clearly invited to participate in a research study?

☐ Yes ☐ No ☐ N/A

Is the subject informed why he/she is being asked to be in the study?

☐ Yes ☐ No ☐ N/A

Purpose:

Is the subject informed why the researchers are conducting the study? This section of the consent form should be restricted to a clear and accurate statement of the scientific purpose and objectives of the research which should help the subject assess the importance of the study relative to individual values.
Yes □ No □ N/A

Description of Procedures:

Is the subject given a description of the study design (i.e. longitudinal, single-blind, double-blind, placebo) and method of subject assignment to groups (e.g. random, criteria based)?

□ Yes □ No □ N/A

Is the subject given a sequential description of each procedure to be applied to human subjects and how often it will be performed? All procedures, both experimental and non-experimental, must be described. Procedures that are experimental should be identified as such. In some research projects it may be appropriate to identify the individual(s) who will perform the procedures or interact with the subject. Suggest a table format, if appropriate.

□ Yes □ No □ N/A

Is the subject made aware of where the research will be conducted, when the research will be conducted, how much time (per session and in total) will be required of the subject, and whether or not the subject will be contacted in the future?

□ Yes □ No □ N/A

Does the research involve deception or incomplete disclosure? If so, potential subjects should be advised on the consent form that the information they are given may not complete and that they will be debriefed after the research procedures are completed.

□ Yes □ No □ N/A

If the research involves questionnaires, surveys, or interviews, does the consent form provide an adequate description of the types of questions that will be asked, or the topics covered?

□ Yes □ No □ N/A

Is the subject made aware of any medications, therapeutic regimens, foods or other substances that are contraindicated or disallowed either before or during participation in the study (e.g. drug “washout”)?

□ Yes □ No □ N/A

Is the subject made aware that he/she may be audio or video-taped?

□ Yes □ No □ N/A

If the study is a placebo-controlled study, is the subject provided information related to rescue therapy and any details needed?

□ Yes □ No □ N/A

Risks and Inconveniences:

Is the subject informed of any risks (physical, psychological, social, or economic) as a result of study procedures? Each procedure or intervention should be identified and then the associated risks described. Identify both immediate and latent risks of each procedure or intervention carried out for research purposes. Identify steps taken to minimize risks.

□ Yes □ No □ N/A
Is the subject informed of any inconveniences (e.g. the amount of time to complete the survey/interview) as a result of the study procedures?

☐ Yes ☐ No ☐ N/A

Are the risks listed in appropriate order from most likely to least likely to occur (with some sort of rating incidences of risks)?

☐ Yes ☐ No ☐ N/A

If there are no known risks, is this stated? “There are no known risks associated with this research” is an acceptable statement.

☐ Yes ☐ No ☐ N/A

When appropriate, does the consent form include a statement that the research may involve risks that are currently unforeseeable?

☐ Yes ☐ No ☐ N/A

For studies involving investigational drugs or devices, does the consent form describe a means whereby information about the drug or device may be obtained in emergency situations?

☐ Yes ☐ No ☐ N/A

For research involving pregnant women, are risks (known and unknown) to the fetus adequately described?

☐ Yes ☐ No ☐ N/A

If applicable, does the consent form contain a statement indicating 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?

☐ Yes ☐ No ☐ N/A

Benefits:

Does the consent form clearly describe any direct benefits to the subject that may be reasonably expected as a result of participation in the study? The potential benefits to the subject must not be overstated, coercive, or guaranteed. If there is no individual benefit, the consent form should state this.

☐ Yes ☐ No ☐ N/A

Does the consent form clearly describe any benefits expected to accrue to the population the subject represents or to society in general (e.g. advancement of knowledge, health benefit to others)?

☐ Yes ☐ No ☐ N/A

NOTE: Payment for participation or other incentives and gifts are not considered to be research benefits and should not be listed in this section.

Economic Considerations:

Does the consent form describe any and all compensation to subjects (including direct payment or reimbursement for costs such as travel, parking, etc.) and the conditions for receiving this compensation? Compensation should not be coercive in amount or method of distribution and may not be based on the
completion of the study and it should be stated within the consent the compensation provided if participants are unable to complete the study.

☐ Yes ☐ No ☐ N/A

Does the consent form clearly list any drugs, tests, procedures, etc. that are required elements of participation and that are not paid for by the investigator or sponsor? If these elements are provided free of charge this should also be stated. In addition, is it made clear that the subject and/or his or her insurance provider will be liable for costs not covered by the investigator or study sponsor?

☐ Yes ☐ No ☐ N/A

Does the consent form clearly list other costs (transportation to and from the study site, childcare, etc.) the subjects may incur as a result of participation? For certain populations, of subjects, such as those who are economically disadvantaged, these costs may impact an individual’s choice to participate in the study.

☐ Yes ☐ No ☐ N/A

For research studies involving Tulane University students as subjects, does the consent form describe the specific amount of extra credit subjects can earn for their participation?

☐ Yes ☐ No ☐ N/A

**Alternate Treatments and Alternatives for Participation:**

If the study offers treatment, does the consent form describe what alternatives exist to the treatment offered per the study? When appropriate, the relative risks and benefits of the treatment alternative vs. the research should be stated.

☐ Yes ☐ No ☐ N/A

If the subjects are Tulane University students who will receive academic credit, does the consent form describe the alternatives available (comparable in terms of time, effort, and educational benefit) to earn equivalent academic credit.

☐ Yes ☐ No ☐ N/A

If the study does not offer treatment and no alternatives exist then this section should be omitted.

**Confidentiality:**

Does the consent form provide a thorough outline of the procedures in place to ensure the confidentiality of the subject’s participation and of the study data (e.g. where study records will be stored, how long records will be kept, etc.)? Does the consent form adequately describe the procedures to ensure confidentiality of any electronic data?

☐ Yes ☐ No ☐ N/A

Does the consent form list who will have access to the study records? If subjects will be audio or video taped, does the consent form describe who will transcribe the tapes and how long the tapes will be kept?

☐ Yes ☐ No ☐ N/A

Does the consent form contain the following required statement: “You should know that the Tulane University Human Research Protection Office, Biomedical or Social/Behavioral Institutional Review Board (IRB) may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your
responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.”

☐ Yes  ☐ No  ☐ N/A

If study data is to be released, does the consent form state that the person(s) or agency to whom information will be furnished, the nature of the information to be furnished, the purpose of the disclosure and whether the subject’s name will be used? This is particularly important for certain vulnerable populations including students and employees of Tulane University.

☐ Yes  ☐ No  ☐ N/A

If a Certificate of Confidentiality is required for the study, does the consent form state this, as well as provide a description of the extra protection (and limitations to such protection) that is afforded?

☐ Yes  ☐ No  ☐ N/A

Does the consent form describe any situations in which confidentiality cannot be guaranteed (such as reporting requirements for abuse, positive HIV/AIDS diagnosis, etc.)?

☐ Yes  ☐ No  ☐ N/A

Does the study involve genetic testing? If so, are the relevant confidentiality issues (how samples will be stored, withdrawal of samples, plans for return of information to subjects, etc.) addressed? Also, is there a procedure in place to agree or refuse genetic testing?

☐ Yes  ☐ No  ☐ N/A

Note: If the researcher is employing study procedures that will obtain and disclose Protected Health Information (PHI) from the study participant, it may be necessary to ask subjects to sign an authorization to allow use of the PHI. Contact the Research Compliance Officer for additional information at 504-988-1147

In Case of Illness or Injury:

If the study presents a greater than minimal risk of injury or illness to the subjects, does the consent form include a statement telling subjects what they should do if they become sick or injured (go to ER, call PI, etc.). If funds exist to reimburse the subjects for the cost of their medical treatment, this must be stated. If no funds exist to reimburse subjects, this must also be stated.

☐ Yes  ☐ No  ☐ N/A

If there is a greater than minimal risk of injury or illness to the subjects, does the consent form include the following required statement:

“In the event you become sick or injured during the course of the research study, immediately go to the emergency room and notify the principal investigator or a member of the research team. If you require medical care for such sickness or injury, your care will be billed to you or your insurance company in the same manner as your other medical needs are addressed.

The Tulane University Health Sciences Center and the investigators in this protocol will provide necessary medical treatment for any injury or illness which may arise from your participation in this research. However, such treatment will be on a fee for service basis.”

☐ Yes  ☐ No  ☐ N/A
Does the consent provide the statement, “You will be provided an emergency evacuation and wallet card to be carried with you in case of emergency that will include study title, investigator contact, and IRB contact information.’

☐ Yes  ☐ No  ☐ N/A

For industry sponsored studies, does the sponsor assume the costs of care associated with injuries incurred as a result of participation in a properly executed protocol?

☐ Yes  ☐ No  ☐ N/A

*Note: If the study includes no procedures with more than minimal risk of illness or injury to the subjects then this section may be omitted.*

**Voluntary Participation:**

Does the consent form include the following required statement: “You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.”

☐ Yes  ☐ No  ☐ N/A

For certain vulnerable populations it may be necessary to expand upon the “no penalty” statement. If Tulane students will be enrolled a statement indicating that their “academic standing will not be affected” if they decline to participate should be included within the consent form. If AIDS patients will be enrolled through a clinic, a statement should be included indicating that the services they receive through the clinic, “will not be taken away or changed” if they decline to participate.

If applicable, the subject must be informed that he or she may be withdrawn from the study at any time, and, if appropriate, given the conditions for such a withdrawal (e.g. adverse events, non-adherence to protocol instructions, etc.)

**Questions:**

Does the consent form include the following required statement: “Take as much time as you like before you make a decision to participate in this study. We will be happy to answer any questions you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator (insert name and phone number) or the student researcher (insert name and phone number). If you have any questions concerning your rights and as a research participant, you may contact the Tulane University Research Compliance Officer at 504-988-1147 or via email at researchcompliance@tulane.edu.”

☐ Yes  ☐ No  ☐ N/A

**Authorization:**

If the study is confidential (meaning that the subject’s identity is known and linked to the data) then the signature authorization section, to obtain written consent, is required.

Does the consent form include the following required statement: “I have read this form and decided that I will participate in the research project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.”

☐ Yes  ☐ No  ☐ N/A
Does the consent form, include a signature and date line for the subject or their legal guardian to complete, as well (if applicable)? Also, does the consent form include a signature line for the PI or the person obtaining consent?

☐ Yes ☐ No ☐ N/A

Additional Considerations:

For studies involving Non-English subjects, has the consent form been translated into all relevant languages?

☐ Yes ☐ No ☐ N/A

If appropriate, is the subject informed of the approximate number of subjects involved in the study?

☐ Yes ☐ No ☐ N/A

Is subject informed they will be provided with a copy of the consent form?

☐ Yes ☐ No ☐ N/A

Consent/Assent Procedures for Children Involved as Research Subjects:

The Federal government has issued special guidance regarding children engaged as subjects in research. IRBs need to carefully consider whether or not adequate provisions have been made to obtain assent of the children to participate in the study. While assent of the child is always a requirement, the IRB and the researchers must, under Federal guidelines, consider the children's ages, maturity level, and psychological state. Generally, if the research involves minor subjects under the age of 7, only a parental consent form is required. In some cases where the research is greater than minimal risk (45 CFR 46.406 and 46.407) consent of both parents may be required.

If the subject is 7-12 years of age, a Child Assent Script is required. This assent script should describe the study to the children in language they would understand. Given this age range, the IRB would consider oral assent appropriate.

If the subject is 13-17 years of age, written assent is appropriate. A separate assent form may be prepared for the minor to sign in addition to the parental consent form. Again, the study should be described to the minor subject in language they would understand.

Waiver/Alterations of Informed Assent:

Per Federal Regulations, the IRB determined that it can waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) 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

(2) That the research presents no more than minimal risk of harm to subjects and involves procedures for which written consent is not normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Under justified circumstances, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent. Before a
waiver can be issued for non-exempt research, the IRB must determine that all of the following conditions exist as per Federal Regulations:

(1) The research or demonstration project is to be conducted by, or subject to the approval by, state or local government officials, and is designed to study, evaluate or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs and

(2) The research could not practicably be carried out without the waiver or alteration.

OR

(1) The research involves no more than minimal risk to the subject;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not be practicably be carried out without the waiver or alteration; and

(4) If possible, the subject will be fully informed after the project has been completed.