12.1 Executive Summary
This document provides information regarding the Informed Consent process for research involving human subjects. This document contains information regarding NC State University’s IRB policy, standard operating procedures, and terms and definitions. This document outlines the processes that researchers should follow when determining the most appropriate manner for implementing Informed Consent for the proposed study and any considerations that the IRB will make regarding communication of Informed Consent, Continued Consent, and Waiver of Consent.

12.2. Policy
When completing research with human subjects, all NC State faculty, staff, students, or others acting on behalf of NC State, must obtain Informed Consent in accordance with 45 CFR 46.116 – 117 from participant’s or their legally authorized representative unless the IRB has granted a waiver of consent. This includes informed consent, parental permission, and minor assent documents. All procedures related to the informed consent process must be documented within the approved IRB protocol and supplemental approved documents. The IRB will evaluate all forms and processes for obtaining and documenting informed consent, parental permission, and minor assent.

12.3. Standard Operating Procedure (SOP)
The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for by the Federal regulations and the NC State IRB. Investigators are required to obtain legally effective informed consent from a subject or the subject’s Legally Authorized Representative unless the requirement has been waived by the IRB. When informed consent is required, it must be sought prospectively, and properly documented. The informed consent process begins when the participant first learns of the study through recruitment, continues through formally requesting consent to be in the study through written or verbal communication, and then continues through voluntary participation within a research environment promoting a culture of voluntariness, data destruction and publication of findings.

12.3.a. Informed Consent Process and Form
In accordance with 45 CFR 46.116, Informed consent must be obtained under the following circumstances:

i. Informed consent is a process by which the interests and the concerns of the participant are centered in the information you give and conversations that you have. The purpose of this consent process is to give the participant or representative all of the relevant information that will help them decide whether or not participating in the research is a good fit for them. Throughout the Informed Consent process, information must be presented in a manner that is consistent, organized, avoids jargon, comprehensible to the individual, and provides some way for participants or their representative to ask questions.

ii. The informed consent process provides the prospective subject (or legally authorized representative) with sufficient opportunity to read the consent document, when applicable. This
means that participants must have the time and resources to properly consider the risks, benefits, and time required to be in the study.

iii. The informed consent process shall be sought under circumstances that provide the subject (or legally authorized representative) with sufficient opportunity to consider whether or not to participate.

iv. The informed consent process shall be sought under circumstances that minimize the possibility of coercion or undue influence.

v. The investigator is responsible for ensuring that each prospective subject is adequately informed about all aspects of the research and understands the information provided. This responsibility starts with recruitment and ends when the study is complete.

vi. When using an Informed Consent Form, informed consent may only be obtained from subjects who have the legal and mental capacity to give consent. For subjects without that capacity, permission must be obtained from a legal guardian or a legally authorized representative (see Appendix A).

vii. The information on the Informed Consent Form must present in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.

viii. The Informed Consent Form must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

ix. The information on the Informed Consent Form must be presented in language that is understandable to the subject (or legally authorized representative). To the extent possible, the language should be understandable by a person who is educated to 6th grade level and layman’s terms shall be used in the description of the research.

x. For subjects whose native language is not English, informed consent must be obtained in a language that is understandable to the subject (or the subject’s legally authorized representative). In accordance with this policy, the IRB requires that informed consent discussions include a reliable interpreter when the prospective subject does not understand the language of the person who is obtaining consent.

xi. The Informed Consent Form may not include any exculpatory language through which the subject is made to waive, or appear to waive, any of the subject’s legal rights.
12.3.b. General Requirements for Informed Consent

Legally effective informed consent must be sought from each potential subject or the subject’s legally authorized representative, in accordance with, and to the extent required by, 45 CFR 46.116. The consent document must include both the basic elements of informed consent, and as appropriate, additional elements of informed consent.

i. The basic elements of informed consent are:
   1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental
   2. A description of any reasonably foreseeable risks or discomforts to the subject
   3. A description of any benefits to the subject or to others that may reasonably be expected from the research
   4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
   5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
   6. 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
   7. 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
   8. 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
   9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
      a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
      b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

ii. Additional elements of informed consent to be applied, as appropriate:
   1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

12.3.c. Parental/Guardian Permission and Minor Assent

i. Definitions:
   1. Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
   2. Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
   3. Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.
   4. Parent means a child's biological or adoptive parent.
   5. Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

ii. Permission from Parents and Guardians, Minor Assent
   1. Minor Assent:
      a. In accordance with 45 CFR 46.408 the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.
      b. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.
      c. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the
context of the research, the assent of the children is not a necessary condition for proceeding with the research.

d. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

e. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

f. Regarding inclusion of minors attending institutions of postsecondary higher education, please refer to NC State Policy 8.

2. Parental/Guardian Permission

a. The IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian.

b. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted is minimal risk or has direct benefits to the minor (45 CFR 46.404-405).

c. Where research is more than minimal risk or otherwise not approvable (45 CFR 46.406-407) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

d. If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

e. Permission by parents or guardians shall be documented

12.3.d. Translation of Forms for Non-English Speakers

i. Official Translations. When the investigator can anticipate enrollment of persons who do not speak or read, or have limited proficiency in oral or written English, or the investigator otherwise anticipates that consent will be conducted in a language other than English, the IRB requires a translated consent document, and other subject materials, to be prepared. For studies reviewed at the Expedited or Full Board level, a translation verification form must be submitted. In some cases, the IRB may request an additional translation certification.

ii. Unless the person obtaining consent is fluent in the prospective subject’s language, an interpreter will be necessary to facilitate the consent discussion. Preferably someone who is independent of the subject (i.e., not a family member) should assist in presenting information and obtaining consent. Whenever possible, interpreters should be provided copies of the translated consent, or short form and the IRB-approved consent script (typically the English-language version of the consent document) well before (24 to 48 hours if possible) the consent discussion with the subject. If the interpreter also serves as the witness, she/he may sign the translated consent, or short form consent document and script, as the witness and should note
“Interpreter” under the signature line. The person obtaining consent must document that the “short form” process was used in the subject's research record, including the name of the interpreter.

12.3.e. Waivers, Alteration, and Documentation of Consent

i. An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:
   1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern
   2. That 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
   3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
   4. An electronic signature where a participant types their name onto the consent form is considered acceptable documentation for most research projects.
   5. “Clicking yes/no” to consent requires a request to waive documentation of written consent.

ii. An IRB may waive the requirement to obtain informed consent for research or may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent, provided the IRB satisfies all of the requirements below. In order for an IRB to waive or alter consent the IRB must find and document the five criteria noted below (see Appendix B for details):
   1. The research involves no more than minimal risk to the subjects
   2. The research could not practicably be carried out without the requested waiver or alteration
   3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using them in an identifiable format
   4. The waiver or alteration will not adversely affect the rights and welfare of the subjects
   5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

iii. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable (see section 12.3.g. below), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
iv. If consent has been collected, and an opportunity arises to use data from the approved research project for activities not listed in the consent form, the researcher must seek IRB approval to re-contact participants in order to get their consent to use their data for purposes not outlined in the consent forms used. If this is not possible, the IRB will determine if the use of the data is within the spirit and scope of the studies purpose and use of data as outlined in the consent forms.

v. An “opt out” form is a letter sent to participants or their legally authorized representative. This letter provides all relevant information about the study. However, instead of the participant or their legally authorized representative consenting to be in the research, they instead default to being in the research and must actively decline participation via an “opt out” form. The use of an “opt out” form is acceptable when the study qualifies for a waiver of consent (See 12.3.e. and Appendix B).

vi. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
   1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
   2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

12.3.g. Broad Consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed study or generated for non research purposes) is permitted. Broad consent can be included as a part of the full Informed Consent Form or by itself. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

i. A description of any reasonably foreseeable risks or discomforts to the subject

ii. A description of any benefits to the subject or to others that may reasonably be expected from the research

iii. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

iv. 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
v. When appropriate: A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

vi. When appropriate: For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

vii. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.

viii. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.

ix. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).

x. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.

xi. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject.

xii. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

12.3.h. Recruitment and Recruitment Materials

i. Recruitment is the first component of the informed consent process. The IRB must review and approve any and all advertisements and communications prior to posting and/or distribution for all studies. The IRB will review the information contained in the advertisement, the method of communication, the final copy of any print or online advertisements, and the proposed script and final audio/video advertisements. Recruitment materials should be limited to the information the prospective participant needs to determine their eligibility and interest. The following items should be included:
   1. The name and contact information of the investigator.
   2. The purpose of the research.
   3. The eligibility criteria in summary form.
4. The time commitment required of the participants.
5. The location of the research.
6. A clear statement that this is research and not treatment.
7. A brief list of potential benefits.

ii. The IRB reviews the material to assure that the material is accurate and is not coercive or unduly optimistic, creating undue influence to the subject to participate. Recruitment materials should not include:
   1. Statements implying a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the research plan.
   2. Emphasis on payment or the amount to be paid, such as bold type or larger font on media or the inclusion of the incentive amount in an email subject line.
   3. The inclusion of exculpatory language.

iii. Once approved by the IRB, an advertisement cannot be altered or manipulated in any way without prior IRB approval.

12.3.i. Environment and Culture of Voluntariness and Partnership

The environment wherein the research takes place and the researcher cultural practices regarding the voluntary nature of research must be free of coercion, undue influence, and promote voluntariness and partnership.

i. Undue Influence. Undue influence occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. In addition to undue influence that can arise with the offering of rewards, undue influence also can be subtle because influence is contextual. Undue influence is likely to depend on an individual’s situation.
   1. Undue influence may come about due to the participant’s environment. Informed Consent may only be sought under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate in the research. This includes considering time and place where participants are recruited, consented, and engaging in research activities.
   2. Undue influence may come about due to an aspect of the study that the participant “just can’t say no to doing” such as free medical care, instruction, or an intervention that is otherwise hard to access.
   3. Undue influence may come about due to people with real and perceived authority over the possible participant. Undue influence may come from people such as parents and guardians, teachers/principals/administrators/case workers, medical care providers, coaches, religious leaders, group leaders, siblings, people with perceived authority or expertise, and public figures such as police, fire fighters, and government officials. When considering the recruitment, consent, and data collection methods, researchers must design their research to manage any aspects of undue influence as a result of power dynamics.
   4. Undue influence may come about due to peer and familial relationships resulting in the feeling of pressure to participate in the research.
5. Undue influence may come about due to compensation. These issues range from type of compensation for participation, amount of compensation participation, and to whom the compensation is given.
   a. This includes addressing when only some people in a group receive said compensation of items or food and others do not.
   b. Consideration as to if the monetary compensation goes directly to the participant or to someone else must be articulated and justified.
   c. The level of remuneration should not be so high as to cause a prospective participant or their legal representative to accept risks that they would not accept in the absence of the remuneration. This same principle would apply to remuneration offered to parents whose minors are prospective subjects.
   d. Protocols submitted to the IRB should indicate and justify proposed levels and purposes of remuneration, which also should be clearly stated in the supplemental consent forms.

ii. Coercion. Coercion occurs when an overt or implicit threat is intentionally presented by one person to another in order to obtain compliance.

iii. Promotion of Voluntariness and Partnership
   1. The researcher should implement a “general inquiry” into the motivations for a person’s decision about enrolling in a study. This not only builds relationships and trust, but it allows the researcher to pay attention to external and intentional influences that may impair voluntariness. Once this information is shared, the researchers can assess the legitimacy of the consent.
   2. The researcher should continually assess the participant’s verbal communication, body language, active participation, and demonstrated interest in being a part of the study.
   3. Researchers should implement routine check points to assess consensual participation and provide reminders of voluntariness.
   4. When completing immersive qualitative research, the researcher has an obligation to maintain boundaries – ensuring the participant knows the difference between what they are consenting to be used as data for research and what they are not.

12.3.j. Revocation of Consent

A participant, their legally authorized representative, or their parent/guardian may revoke consent at any time during the study. Methods to stop participation must be clearly articulated in the Informed Consent Form. Information about revocation of consent and its limitations must be articulated in the Informed Consent Form.

1. Revocation of consent during data collection. When a participant revokes their consent during data collection, all procedures should be halted and their data destroyed unless destruction of data is impossible or the participant has requested it not be destroyed.
2. Revocation of consent when data collection is completed. When a participant revokes their consent after data collection is completed, their data should be destroyed unless destruction of data is impossible or the participant has requested it not be destroyed.
3. Revocation of consent once data is published. It should be clear in the initial consent process that revocation of consent once the study is completed and published is not possible. However, their data should be destroyed or the participant has requested it not be destroyed.
Appendix A
Legally Authorized Representative

Federal regulations that govern research involving human subjects define a legally authorized representative (LAR) as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

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

1. Court-appointed legal guardian
2. A health care power of attorney (HCPOA)
3. A durable general power of attorney
4. In the event that there is neither a court appointed guardian nor an agent under a durable general power of attorney or HCPOA, surrogate consent for research may be given by the other individuals listed below, in order of priority.
   a. The subject’s spouse;
   b. A majority of the subject’s reasonably available parents and adult children;
   c. A majority of the subject’s reasonably available adult siblings; or
   d. Another individual with an established relationship with the subject who is acting in good faith on behalf of the subject and can reliably convey the subject’s wishes.
Appendix B
Details Regarding Waiver of Consent Criteria

The research involves no more than minimal risk to the subjects

- Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - define a threshold of anticipated harm or discomfort associated with the research that is "acceptably-low" or "low enough"
  - harms and discomforts of the research should consider the nature of the study procedures, other study characteristics, subject characteristics, and steps taken to minimize risk
  - consider the characteristics of subjects to be enrolled in the research including an evaluation of subject susceptibility, vulnerability, resilience and experience in relation to the anticipated harms and discomforts of research involvement
  - the estimate of the anticipated harms and discomforts of the research for the proposed study population may not be greater than an estimate of "the harms and discomforts ordinarily encountered in daily life or during the performance of routine medical and psychological examinations or tests"
    - an ethically meaningful notion of "harm and discomforts ordinarily encountered" should reflect "background risks" that are familiar and part of the routine experience of life for "the average person" in the "general population." It should not solely be based on those ordinarily encountered in the daily lives of the proposed subjects of the research or any specific population.
  - minimal risk should be applied in manner that recognizes that risks are procedure-specific and population-dependent, but that the notion of acceptably-low risk is fixed. When the harms and discomforts of the proposed research as they are anticipated to impact the study participants are judged to fall below this acceptably-low risk threshold, the research is said to be "minimal risk."

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

The commonly accepted definitions of the term "practicable" are (a) feasible; (b) capable of being effected, done or put into practice; and (c) that may be practiced or performed; capable of being done or accomplished with available means or resources.

It should be noted that this criterion states that the research could not practicably be carried out without the waiver or alteration. Put another way, it would not be practicable to perform the research (as it has been defined in the protocol by its specific aims and objectives) if consent were required. The emphasis being that it is impracticable to perform the research, and not just impracticable to obtain consent. The justification must provide a reasonable rationale for why the research would not be possible without the waiver.

The following concepts may help an IRB determine whether the research could not be practicably carried out without the waiver of consent:

- Scientific validity would be compromised if consent were required.
- Ethical, legal, or risk related concerns would be raised if consent were required.
● There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.
● Practicability should not be determined solely by considerations of convenience, cost, or efficiency.

If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using them in an identifiable format

● A justification is required as to why identifiers are required to be directly on the data or linked to the data via a master list.
● Examples of scientific rationales include sharing results with participants and longitudinal studies.

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

● Whether there are other federal, state, or local laws that provide rights to potential subjects to require informed consent. IRBs should seek advice from their legal counsel when appropriate to help the IRB with these determinations. This would be especially important for state specific regulations.
● Whether the subject population, in general, would object if they knew of the waiver and its intent in facilitating research.
● Whether the subject population, in general, would consider that the waiver has the potential to cause adverse consequences for their welfare or general well being.

Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

● This criterion is intended to refer to the need to consider debriefing after research is conducted. In these situations it may be ethically required or determined to be respectful to provide the subject with pertinent information after the research is complete. IRBs may want to consider this mechanism when subjects are included in "deception research," in which some aspects of the study are not fully disclosed upfront so that subject responses are not biased.
● Under most circumstances, this criterion does not apply to retrospective research conducted under a waiver (e.g., review of existing records).