**Informed consent**

Informed consent is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. It is both an initial and ongoing process, not just a form or document, which enables prospective and current research participants to voluntarily decide whether or not to participate as a research subject, or to continue participation.

**Description and procedures**

With few exceptions (other than research determined to be exempt), no investigator may involve a human being as a subject in research at DeSales unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative PRIOR to participation and appropriately documented the informed consent process.

DeSales IRB Committee has developed a written Informed Consent Template that provides investigators with guidance in developing an informed consent document. The template, format, and language have been approved by the DeSales IRB. This template is drafted to include all 8 required elements of informed consent that are provided in both DHHS and FDA regulations as well as the additional elements. Certain elements may simply not apply to the research (particularly in low risk studies). However, every effort should be made to include any and all elements, which add to the research subject’s understanding, regardless of how significant it may be.

It should be noted that the intentional exclusion, omission, or alteration of some or all element of the informed consent process requires justification. This justification process supports a “waiver of some or all elements of informed consent” When only certain elements are waived, they are considered individually. When all elements of informed consent are waived, they are considered both individually and collectively.

**Informed Consent Process**

The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate).

Adequacy of consent is of great importance. The following points are detailed within the regulations:

* An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence
* The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.
* No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The DeSales IRB has the authority to observe or have a third party observe the consent process and the research.

**Elements of Consent:**

The BASIC and ADDITIONAL requirements for informed consent (as dictated by federal regulations) are quoted below. The DeSales IRB requires that the basic elements, required by regulation, be provided to human participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects. These elements must appear within the consent form for both expedited and full board review that is either biomedical or social-behavioral-educational research. The biomedical or social-behavioral informed consent template provides sample language for framing the elements according to the type of research. Note that element #6 below applies only to research that is greater than minimal risk and is therefore not applicable to inclusion in a consent form for expedited review research.

**Basic Elements of Consent 45 CFR 46.116(a) and 21 CFR 50:**

§46.116(a) General requirements for informed consent:

Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

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 which 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 which 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 (and that notes the possibility that the Food and Drug Administration may inspect the records - if the research is FDA-regulated);
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; and
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.

In addition to the above basic elements of informed consent, for each of the following additional elements of informed consent disclosure the DeSales IRB requires:

* If the risk profile of any research-related interventions is not well known or the research involves investigational drugs or devices: A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable must be provided.
* If the research includes women of child bearing potential or pregnant women, and the risk profile of any research interventions or interactions on embryos and fetuses is not well known: A statement that the particular treatment or procedures may involve risks to the embryo or fetus, if the participant is or may become pregnant, which is currently unforeseeable must be disclosed.
* If there are anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent: Anticipated circumstances under which the participant may be terminated by the investigator without the participants' consent must be provided.
* If there are costs to the participant that may result from participation in the research: Additional costs associated with study participation must be disclosed.
* If there are adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research: Consequences of a participant's decision to withdraw from the research.
* If there are adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research: Procedures for an orderly termination of participation must be provided.
* Unless significant new findings during the course of the research which may relate to the participant's willingness to continue participation are unlikely: Statement that new findings developed during the course of the research that may relate to the participant's willingness to continue in the research study will be provided to the participant.
* Unless the approximate number of participants involved in the study is not important to a decision to take part in the research: Approximate number of participants involved in the study.
* Incorporation of relevant state law requirements into the informed consent process, including: 1) vulnerable subjects and consent or permission on their behalf, 2) mandatory reporting requirements to designated authorities, 3) definition of ‘child’ and those who may give permission or consent on the child’s behalf.

**Additional Elements 45 CFR 46.116(b) and 21 CFR 50:**

§46.116(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

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) which are currently unforeseeable;
2. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject'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 which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. the approximate number of subjects involved in the study.

**Waiver of Some or All Elements of Informed Consent:**

The IRB may approve a consent procedure, which does not include, or which alters some or all of the elements of informed consent in accordance with the following two regulatory citations from 45 CFR 46:

**45 CFR 46.116(d)**

*NOTE: 45 CFR 46.116(d) for waiver of some elements or all elements of informed consent is used more frequently at DeSales and most typically involves research that is very low risk and certainly no greater than minimal risk.*

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

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

Explanation of the findings related to waiver of all, or some, of the elements of informed consent:

* Waiver of some, or all, elements of informed consent applies to research that qualifies for EXPEDITED review, and is non-FDA regulated research only, since the research may be no greater than minimal risk.
* Carefully consider the question of whether rights and/or welfare of subjects is impacted by not being informed, or fully informed, of involvement in a research study
* “Practicability” does not mean convenience, rather it refers to genuine feasibility
* If it is appropriate to provide a ‘debrief’ or an explanation about the research AFTER it has involved the participant, the PI must submit such information by way of a written form or letter or as a verbal script for IRB approval.
* The waiver of some or all elements of informed consent need not apply to each and every research participant in the study, depending on the research design. In cases where only some participants are eligible for waiver of consent, the PI should describe these participants, as well as, provisions for providing informed consent at a later time. Such scenarios may be captured in a process wherein the participant gives consent for continued participation.

**45 CFR 46.116(c)**

*NOTE: 45 CFR 46.116(c) for waiver of some elements or all elements of informed consent is not used frequently at DeSales since the situation deals with specialized government programs.*

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

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (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; or (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.

**Modification of the Informed Consent Document:**

The consent document must be revised when deficiencies are noted or when additional information will improve the consent process (this helps ensure ongoing informed consent). If revisions are significant, the PI and/or the IRB will require that currently enrolled subjects sign the new informed consent.