General Policy

Researchers must describe in the research protocol how the informed consent process will be conducted, the setting in which it will occur, a description of the waiting period between informing the prospective participant and obtaining consent, and methods to prevent undue influence on a potential participant to enroll in a study. The following are points to consider when conducting the consent process.

- Researchers should consider obtaining informed consent as a process, not just a consent form, by which the research study is thoroughly explained to the potential subject. The requirement to obtain informed consent should be seen as not only a legal obligation, but also as an ethical obligation. Documentation of informed consent is accomplished through the use of a consent form. Prior to
enrolling subjects in a research activity, researchers are required to obtain legally effective informed consent from a potential subject or their legally authorized representative (LAR) and, if the research involves children, a parent's consent and child's assent.

- As part of the informed consent process, researchers are responsible for ensuring subjects (or LARs) are given sufficient opportunity to consider whether or not to participate in the study and must seek to avoid coercion or undue influence. Information given to potential subjects (or LARs) must be in language that is understandable to the subject or representative. Non-English speaking subjects must have information presented in a language they understand. In addition, for all studies that pose a real or foreseeable risk of biomedical harm, California state law (Health and Safety Code section 24172) requires that the Experimental Subject’s Bill of Rights be provided to all subjects "written in a language in which the subject is fluent."

- No process or consent form used to obtain and document consent may include exculpatory language through which the subject waives any of their legal rights or releases, or appears to release, the researcher, sponsor, or institution or its agents from liability for negligence. Any consent form used to enroll subjects in a research protocol must be reviewed and approved by an IRB prior to enrollment. In addition, the IRB may request to observe the informed consent process to ensure adequate consent when the research involves particularly vulnerable populations.

- Researchers should be aware that the setting in which consent is sought may introduce a feeling of undue influence. For example, students in an educational setting may feel that refusal to participate will affect their grades. Prevention of these sorts of pressures should be addressed in the research design as the process must always preserve the right to refuse participation.

- In all cases, consent forms must be consistent with state laws and federal regulations regarding content. The informed consent requirements stated in this manual are not intended to preempt any applicable federal, state, or local laws that require additional information be disclosed in order for informed consent to be legally effective.

- The Revised Common Rule allows the use of broad consent (e.g., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens.
  - Broad consent will be an optional alternative that an investigator may
choose instead of, for example, conducting the research on nonidentified 
information and nonidentified biospecimens, having an institutional 
review board (IRB) waive the requirement for informed consent, or 
obtaining consent for a specific study.

- Whether or not identities are removed, the consent must state:
  - unspecified future research may occur without additional consent;
  - or that the information or biospecimens will not be used for future
  research

Elements of Informed Consent
The IRB will determine that the required disclosures will be provided to each subject or
a LAR in accordance with legal and regulatory requirements listed below as required
elements of informed consent. The IRB will also consider whether additional disclosures
are required for inclusion in the consent process.

It is expected that researchers will use the informed consent form template with
required sections and verbiage for preparing consent forms. Other formats may be
considered providing that all required elements and applicable additional elements are
present. Research-related consent forms must contain all the basic elements of
informed consent regardless of the risk level of the study unless a request for waiver or
alteration of some or all of the elements is requested by the researcher and the waiver
is approved by the IRB. The consent form template contains all the required elements of
consent. In addition, the IRB requires that all consent forms be written at a level
appropriate to a minimum expected educational level of the target population and in
the second person (e.g., "You will be asked to..."). The following are the basic required
elements (extracted from 45 CFR Part 46.116):

1. A statement that the study involves research.
2. An explanation of the purpose of the proposed research.
3. The expected duration of the subject's participation.
4. A description of the procedures to be followed.
5. Identification of which procedures are experimental. For studies that are not
greater than minimal risk and are not HHS-funded, this element may be omitted.
6. A description of reasonably foreseeable risks or discomforts that subjects may
encounter and, if appropriate, a statement that some risks are currently
unforeseeable.
7. A description of possible benefits, if any, to the subject and others that may
be reasonably expected. It should be stated that no benefits can be
guaranteed for experimental treatments or procedures.
8. A disclosure of appropriate alternative procedures or treatments, if any, which
are available and might be advantageous to the subject. One alternative might
be to choose not to participate in the research. For studies that are not greater
than minimal risk and are not HHS-funded, this element may be omitted.

9. A statement describing the manner and extent, if any, to which confidentiality of records identifying the subject will be maintained, a statement that the IRB and other entities may inspect the records, and, if the research is Food and Drug Administration (FDA)-regulated, FDA may inspect the records.

10. For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained. For studies that are not greater than minimal risk and are not HHS-funded, this element may be omitted.

11. A description of whether or not compensation for time, inconvenience, etc. will be given, including the schedule of payments.

12. Information regarding who to contact for answers about the research in the event there is a research-related injury (this is generally the principal investigator (PI) or another staff member closely associated with the study). A separate contact, typically this is the IRB, must be named for questions concerning the subject's rights to provide input, comments, or complaints.

13. A statement that the subjects' participation is voluntary, that refusal to participate will not involve penalty or loss of benefits to which the subject is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled.

Note: for FDA regulated applicable clinical trials the following statement must be included:

"A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

The following additional elements of informed consent must be added to the consent form when appropriate:

1. A statement that the particular treatment and/or procedure may involve risks to the subject (or to the embryo or fetus, if the subject becomes pregnant) that are currently unforeseeable. This element should be included when the research involves an investigational drug or device or involves procedures for which the risk profile is not well known.

2. Anticipated circumstances under which the subject's participation may be terminated by the PI, with or without the subject's consent. Include when there are known circumstances under which the subject's participation may be terminated by the PI or sponsor.

3. A description of additional costs for which the subject will be responsible, that may result from participation in the research study. Include when there are additional costs to subjects, over and above standard of care (e.g.,
additional MRls, radiographs, DEXA scans, visits that may not be covered by insurance/Medicare/Medicaid).

4. A description of the consequences of a subject's decision to withdraw from the research and procedures for orderly and safe termination of participation by the subject. This element should be included when there is a likelihood that abrupt termination from the research is likely to result in adverse events to 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. Include when there is likelihood that interim findings might indicate increased risk and a reasonable person would wish to reconsider participation.

6. The approximate number of subjects that will be involved with the study, totally and at the University. Or other research sites. Include when such information might affect a subject's willingness to participate.

7. One of the following statements about any identifiable private information or identifiable biospecimens:
   - 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 LAR;
   - or 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.

8. Other additional information may be required by the IRB.

Other Requirements for Obtaining Informed Consent

1. The IRB must be made aware of the person(s) who will be conducting the informed consent process. These researchers should be listed in the application and are the only personnel allowed to obtain consent. The IRB requires that the person obtaining consent be appropriately trained in human subjects research and fully knowledgeable about the project and be able to answer questions that potential subjects may ask regarding the project and/or procedures performed as a part of the project.

2. If potential subjects are deemed as cognitively impaired, informed consent must be obtained from a LAR. They should be told that their obligation is to try to determine what the subject would do if they were competent, or if the subject's wishes cannot be determined, what they think is in the best interest of the cognitively impaired subject. The IRB must approve the inclusion of cognitively impaired subjects.
3. The consent form is only part of the total consent process in which the researcher conducting the informed consent process, perhaps using the written consent form as an outline, describes all facets of the study and answers the subject's questions. The person obtaining consent is responsible for insuring that research subjects understand the research procedures and risks. Each subject (or LAR) must be provided adequate time to read and review the consent form, in addition to being advised of the procedures, risks, potential benefit, alternatives to participation, etc. Failure of the subjects to ask questions should not be construed as understanding on the part of the subject.

4. The IRB has the authority to observe the consent process at any time. Depending on the perceived risk of the research procedures, the IRB may wish to observe the consent process for that protocol. In these cases, the PI will be contacted and the time and place for observing the process will be scheduled.

5. Obtaining informed consent from subjects must be accomplished prior to performing the research activity and using only an IRB-approved consent form. Written requests for amendments to an existing consent form must be approved prior to implementation, at which time the revised consent form will be stamped with an approval date by the IRB Administrator and be accompanied by a formal approval notification.

6. Upon receipt of an IRB approved consent form, copies of all old versions should be discarded to prevent inadvertent use of an outdated consent form. Copies of the most recently approved consent form may be made and should be used until superseded by an amended consent form. The consent form must be reviewed at least annually as part of the continuing review process. It is advised the researchers retain a copy of the original, expired consent form(s) for their records.

7. For long-term studies, researchers are reminded that the informed consent process is ongoing and that it does not end with the signing of the consent form. Subjects should be kept apprised of events that might affect their willingness to participate.

**Documenting Informed Consent**

Federal regulations governing the use of human subjects in research activities require written documentation of informed consent (handwritten signature of the subject) unless the research meets the criteria for waiver of documentation. The subject and research staff member administering the consent process should sign and date the IRB approved consent form.

1. After completing the consent process and assuring that the subject (or LAR) has
no further questions and agrees to participate in the research activity, the person obtaining informed consent should instruct the subject (or LAR) to sign and date the consent form in the appropriate spaces.

2. The researcher or designee conducting the consent process must then sign and date the consent form in the appropriate space. It is assumed that in most cases, all persons signing the consent form will do so at the conclusion of the consent process.

3. Each subject (or LAR) must be given a copy of the signed consent form. The original consent form should be filed in such a manner as to insure immediate retrieval when required by auditing entities, e.g., OHRP, FDA, IRB.

Non-English Language Informed Consent and other Study Documents

It is neither ethically justifiable to exclude potential subjects in a research study solely on the basis of language spoken nor ethically justifiable to obtain consent of subjects who do not have a clear understanding of the consent document or who do not have the opportunity to freely ask and receive answers to their questions. Without this understanding and opportunity, consent may not be truly informed and may not be legally effective. In order to address these considerations, when enrolling subjects who do not speak English in research, the subject must be provided with:

1. A written consent document in a language understandable to them.
2. An interpreter fluent in both English and the subject’s spoken language.

A consent form translated into the appropriate language should be submitted to the IRB.

Translation Requirements:

- **Greater than minimal risk studies:** a professional or certified translation of the consent/assent form(s) and recruitment material(s) is required for studies that pose more than minimal risk to subjects (i.e., studies that require full committee review), unless the IRB has granted a waiver of documentation of informed consent.
  
  o For a professional translation the PI must provide the qualifications of the individual who translated the informed consent documents and recruitment materials. Include any credentials, certifications, education, native language fluency, etc. For a certified translation, a copy of the certification from the translator or translation service should be attached to the translation of any informed consent documents and recruitment materials.

- **Minimal risk studies:** Studies that are eligible for expedited review also require translation of the consent/assent forms; however, certified translation is not required. The IRB will accept documents translated by an
individual fluent (i.e., can speak, read and write) in a given language. The qualifications of the individual performing the translation will be assessed by the IRB. A letter from the translator describing their qualifications must be provided with the translation documents. As noted above, include any credentials, certifications, education, native language fluency, etc.

Use of a Short Form Written Consent Document
A short form is a written document stating that the elements of informed consent required by 45 CFR 46.116 have been presented to and understood by the subject or the subject's LAR. A short form may be used for an unexpected potential participant does not speak English and there is not enough time to translate the document into a language the research participant understands.

If the majority of the anticipated subjects to be enrolled do not speak English or will be unable to understand the consent form written in English, the consent form must be translated into a language understandable to the subjects.

When following regulations from the Department of Health & Human Services the IRB must determine
1. The consent document states that the elements of disclosure required by regulations have been presented orally to the participants or the participant's LAR.
2. A written summary embodies the basic and required additional elements of disclosure.
3. There will be a witness to the oral presentation.
   For participants who do not speak English, the witness is conversant in both English and the language of the participant.
4. The participant or the participant's LAR will sign the consent document.
5. The witness will sign both the short form and a copy of the summary.
6. The person actually obtaining consent will sign a copy of the summary.
7. A copy of the signed short form will be given to the participant or the LAR.
8. A copy of the signed summary will be given to the participant or the LAR.

When following regulations from the Food and Drug Administration the IRB must determine
1. The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's LAR.
2. A written summary embodies the basic and required additional elements of disclosure.
3. There will be a witness to the oral presentation.
4. For participants who do not speak English, the witness is conversant in both English and the language of the participant.
5. The participant or the participant’s LAR will sign the consent document.
6. The witness will sign both the short form and a copy of the summary.
7. The person actually obtaining consent will sign a copy of the summary.
8. A copy of the signed short form will be given to the participant or the legally authorized representative.
9. A copy of the signed summary will be given to the participant or the legally authorized representative.

**Informed Consent Process for Online Survey-Based Research**
1. Online consent documents should include all the elements of a regular signed consent form.
2. Researchers should maintain the format of the template consent document, with study specific information added, as much as possible.

**Third Party/Surrogate Consent**
1. The regulations are clear that written documentation of informed consent (or consent of the parents if the subject is a child) of the subject (or LAR) is required.
2. When a PI proposes to conduct a research project utilizing adult subjects who by virtue of age, physical impairment, mental impairment, or any other reason may not be able to personally execute legally effective informed consent, the IRB shall review the project on the basis of risk and benefit. This policy is not meant to imply that the requirement for written documentation of consent is waived. Rather, it applies to those studies in which third party/surrogate consent is obtained from a LAR.

**Parental Permission/Assent**
If the research involves minors under the age of 18 years or individuals over the age of 18 who are cognitively impaired, federal regulations require the assent of the child or minor or cognitively impaired adult and the consent of the parent(s) or guardian(s) (45 CFR 46.408). While children and some adults may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent. The assent process should involve taking the time to explain to a child or adult, at whatever age they can begin to understand, what is going on in the proposed study, why the study is being done, what will be done to them, and that if they object, the research will be terminated. Assent means the potential subject's affirmative agreement to participate in the research. Mere failure to object should not, in the absence of affirmative agreement, be construed as assent.

To obtain informed consent for children under the age of 18 years or for adults over the age of 18 who may be cognitively impaired, submit the appropriate adult consent form.

**Waiver of Informed Consent and Waiver of Documentation of Consent**
Waivers cannot be granted for FDA-regulated research and the IRB does not approve requests for "Planned Emergency Research" or exceptions to the requirement to obtain consent for "Planned Emergency Research."

Waiver of Informed Consent
Federal regulations include provisions for approval of a waiver or alteration of part or all of the consent process. There are two general instances when an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 45 CFR 46.116, or waives the requirement to obtain informed consent. In the first general instance (45 CFR 46.116(c)) the IRB must find and document that:

1. The research is to be conducted by or subject to 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 be practically carried out without the waiver or alteration.

In the second general instance (45 CFR 46.116(d)) an IRB may approve a consent procedure that does not include, or that alters some or all of the elements of informed consent or that waives the requirement to obtain informed consent provided that 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 (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent); and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Documentation of Consent
Documentation of consent cannot be waived if the research is FDA regulated.

The IRB has the authority to waive the requirement for written documentation of informed consent. When waiving the requirement for a consent form, the IRB must review a written description of the information that will be provided to subjects and consider whether to require the researcher to provide subjects with a written statement regarding the research. If required, the IRB encourages researchers to use the consent template, or a reformatted version, with the signature sections removed. The IRB may waive the
requirement for the researcher to obtain a signed consent form for some or all subjects if it finds that (45 CFR 46.117 (c)):

1. 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 and the research is not FDA-regulated. 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. 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.

The IRB will also consider granting a waiver of documentation in special circumstances involving international research if the research meets the other regulatory requirements.

The determination of the applicability for waiver of the consent process must be documented in the IRB minutes as to the specific paragraph and subparagraph(s) under which the waiver was approved.

Authorization to Use or Disclose Protected Health Information

In the course of conducting research and/or seeing patients within the University’s programs, Chapman personnel may create or obtain medical information. Please note Chapman University is not a HIPAA Covered Entity. PI’s shall consider the following when handling of protected health information:

- Medical information, along with other personally identifying information, may only be collected and stored in accordance with applicable laws. If you work with or expect to begin working with this kind of data, please contact the Information Security Officer to establish a data security plan that will satisfy the university’s legal obligations. Once a data security plan is implemented, it is important to make sure that you and all of your colleagues working with the data comply with the plan.

- Although the university has numerous legal obligations it must meet in terms of protecting medical information, and even though this data may be referred to as “PHI” (protected health information), a defined term in the Health Insurance Portability and Accountability Act (HIPAA), Chapman is not subject to HIPAA and does not have the systems in place to comply with HIPAA’s requirements.

- Researchers who wish to use HIPAA-protected PHI from a third party in their research should first consult with the Office of Research. That office will consult with Legal Affairs and the Information Security Officer to establish appropriate parameters regarding the types of data that the University can properly accept responsibility for and
what written agreements can be entered into governing use and safekeeping of the
data.

To use or disclose PHI, researchers must obtain an authorization signed by the subjects. Authorization to use or disclosure PHI shall consist of the following required elements:

1. A description of the information to be used or disclosed presented in a specific and meaningful fashion.
2. The name or other specific identification of the person(s), or class of persons, to whom the use or disclosure will be made.
3. A description of each purpose of the requested use or disclosure.
4. An expiration date or event that relates to the individual or the purpose of the use or disclosure.
5. A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization.
6. A statement indicating when the authorization for use and disclosure occurs (e.g., at the end of the research).
7. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

In addition to the core elements, the authorization is required to contain statements adequate to place the individual on notice of all of the following:
1. The individual's right to revoke the authorization in writing, and either:
   a. The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or
   b. To the extent that the Waiver of Informed Consent and Waiver of Documentation of Consent information is included in the notice required by 45 CFR 164.520, a reference to the covered entity's notice.
2. The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected.
3. The authorization must be written in plain language.
4. The individual must be provided with a copy of the signed authorization.

**Waiver of Authorization for Use and Disclosure of PHI**

In order to use or disclose PHI without an authorization signed by the research subject, the researcher must obtain one of the following:

1. Documentation that an amendment or waiver of the research subjects' authorizations, for use/disclosure of PHI has been approved by the IRB. This provision of the rule might be used, for example, to conduct records research when researchers are unable to use de-identified information; or
2. Where researchers represent:
a. That the research is only for purposes of preparing a research protocol or similar uses preparatory to research.
b. That he or she will not remove any PHI from the covered entity and
c. That PHI is necessary for the research purpose; or

3. To disclose PHI of decedents, where the researcher represents that the use or disclosure of PHI is:
   a. Solely for research on the PHI of decedents,
   b. Necessary for the research, and
c. Documentation of the death of the individuals about whom PHI is sought and provided.

Re-Consenting Subjects
Researchers have the responsibility to inform subjects of any new information that might affect subjects' willingness to continue participation in the research. In these cases, an amended consent form, delineating the findings and the changes to the risks or benefits of the research, must be reviewed and approved by the IRB. Subjects should then be briefed on the changes, asked if they wish to continue participation and signify their willingness to continue participation by signing the amended consent form. For minor changes to the consent form that will not change risks or benefits, re-consenting is generally not required.

Record Retention Requirements for Subject Consent Forms
The PI shall maintain, in a designated location, the original copy of all executed subject consent forms. The signed consent forms, along with all research-related files, are to be available for inspection by authorized officials of the University administration, the IRB, regulatory agencies, sponsors and, if applicable, the FDA or HHS. For non-FDA regulated studies, forms should be retained for at least three years after completion of the study. For FDA-regulated studies, all signed subject consent forms shall be retained by the PI for the appropriate period(s) specified below:

1. Drugs: 2 years following the date a marketing application is approved or the study is discontinued.

2. Devices: 2 years after a study is terminated or completed and the records are needed to support FDA approval.

Should a PI or project director depart the University prior to the completion of an activity or less than the time specified above, the PI is responsible for initiating mutually satisfactory arrangements with their department and the University administration as to the disposition of executed subject consent documents.