**Guidance and Template Language on Specific Types of Risk (Biomedical Research Studies)**

Adapted from:*http://ora.research.ucla.edu/OHRPP/Documents/Consent/ICF\_Standards\_Biomedical.pdf*

* **Blood draw risks:** Blood draws may cause temporary discomfort from the needle stick, bruising and, rarely, infection and fainting. If more than one unit of blood is to be drawn within an 8-week period, a medically appropriate precaution concerning subsequent blood donation is required.
* **Ultrasound risks:** Ultrasound imaging has been used for over 20 years. It is based on non-ionizing radiation, so it does not have the same risks as X-rays or other types of imaging systems that use ionizing radiation. Ultrasound imaging is generally considered safe when used prudently by appropriately trained health care providers. Ultrasound energy does have the potential to produce biological effects on the body. Ultrasound waves can heat the tissues slightly. In some cases, it can also produce small pockets of gas in body fluids or tissues (cavitation). The long-term consequences of these effects are still unknown. Because of particular concerns for effects on the fetuses, some medical organizations advocate prudent use of ultrasound imaging in pregnancy.
* **Radiation risks:** Risk from small amounts of radiation exposure is extremely difficult to describe in terms that are meaningful to the average layperson. While comparisons to chest x-rays are often used, most lay people have no way of estimating the risks of exposure from chest X-rays either, even though they are probably familiar with the procedure itself. Use a simple statement that alerts participants to the risk of the radiation exposure and advises him/her to speak with the researcher if there are further concerns about this exposure. The Radiation Use Committee will provide investigators with radiation dosimetry and calculation of the absorbed dose in matter and tissue resulting from the exposure to indirect and direct ionizing radiation.
* **Standard of Care (SOC) Radiation Exposure Risks**: Since the radiation procedures used in this study are all standard of care, the amount of radiation you will receive is the same as that for similar patients who are not participating in this study. Therefore, you will not be exposed to any additional radiation for participation in this study.
* **Non-SOC Radiation Exposure Risks:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. The estimated radiation dose that you will receive as a participant for this type of research has been compared to the limits allowed for a radiation worker. This limit is low and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this study.
* **Radiation Exposure Risk Statement for Studies Requiring Radioactive Drug Research Committee (RDRC) Review**: You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. In addition to the radiation that you may be exposed to as part of your clinical care, you may potentially receive [describe e.g., XXX PET CT scans] in a year while participating in this study.

The US Food and Drug Administration (FDA) has set radiation limits for participants for this type of research. The dose you will receive in this study is low and below these limits and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this study. Please inform your researcher if you have been exposed to radiation as a result of any other research studies.

* **PET Scan - General Risk Statement:** PET scans involve the risks of radiation (see above). If you have had a PET scan or have been exposed to radiation while participating in other research during the past year, you should inform the researcher(s). This will enable the researcher(s) to determine your total radiation exposure and make sure it does not exceed accepted safety guidelines. If you participate in future studies that involve the use of X-rays or radioisotopes, you should discuss the safety guidelines for radiation exposure with the researcher who is performing the study.
* **CT scan risks:** Describe radiation risks from CT scans in the same way as those from x-rays. As with MRI, note the possibility of claustrophobia or discomfort from being in the CT scanner. In addition, include risks and discomforts of contrast agents and sedation if appropriate. CT scans involve the risks of radiation (see above). In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, which may cause symptoms ranging from mild itching or a rash to severe difficulty breathing, shock, or rarely, death. The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may or may not be allowed to have a CT scan or continue in the study. Having a CT scan may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in one position for a long time. If contrast material is used, you may feel discomfort when it is injected [given by XXX]. You may feel warm and flushed and get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache. [List other risks as appropriate to the method by which contrast agent is administered]. [If sedation may be used, discuss risks of sedation here].
* **MRI risks:** Warn subjects that because the MRI machine acts like a large magnet, they must not have any metal on or in their bodies. This precaution is needed to prevent any resulting injury. Also note that subjects will be in a tight confined space and may be bothered by feelings of claustrophobia. They may also be bothered by the loud clanging noise during the MRI scan. Since the risks to a fetus from MRI are unknown, state that pregnant women may not participate in studies involving MRI procedures.
* **Clinical MRI risks**: The MRI procedure uses a powerful magnetic field to generate detailed images of the body. The magnet could move objects within your body that contain metal, such as implants, clips and pacemakers. Tell the doctor if you have any metal items within your body. MRI scanning is painless but you might experience discomfort in the machine. In particular, loud beeping and hammering noises occur during the study when the scanner is collecting measurements. You also may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. You might also experience stimulation of the nerves in your body, which feels like a gentle tap or sensation of mild electric shock. [If appropriate, also discuss the risks of sedation here]. Because the risks to a fetus from MRI are unknown, you cannot participate in this study if you are pregnant.
* **Injection of Gadolinium during Clinical MRI**: Gadolinium, a substance given during the MRI examination, will be given by injection into a vein in your arm. This may cause some minor pain, and may cause some bruising near the area of injection. Gadolinium may also cause headache, nausea, and vomiting. Rarely, it may cause dizziness, rash, itching, or a numb or tingling feeling in the hands or feet, or an allergic reaction. Medical personnel will be available to treat any of these problems if they should occur.
* **Neprogenic Systemic Fibrosis Risk Associated with Gadolinium:** Some people who have had MRIs with gadolinium-based contrast agent gadodiamide have experienced a serious reaction called nephrogenic systemic fibrosis (NSF). NSF is a condition that causes people to develop large areas of hardened skin with lesions called plaques and papules with or without skin discoloration. In some cases, NSF could lead to physical disability and may involve not only the skin, but also the liver, lungs, muscles and heart. The typical patient in whom this has occurred is middle-aged and has end-stage kidney disease.
* **Electromyography:**  Electromyography (EMG) is a low-risk procedure to measure the electrical activity of muscle tissue. Complications are rare. There is a small risk of bleeding, infection and nerve injury where a needle electrode is inserted. When muscles along the chest wall are examined with a needle electrode, there's a very small risk that it could cause air to leak into the area between the lungs and chest wall, causing a lung to collapse (pneumothorax).
* **Reproductive risks (See separate guidance at http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/):** Include among the screening procedures any pregnancy testing done for study purposes. If men or women are advised to use birth control or avoid pregnancy before, during, or after the study, describe these precautions among the study procedures. As appropriate, identify any required or acceptable methods of birth control and describe the risks to pregnant mothers, fetuses, and/or fertility of subjects.
* **Known reproductive risks (See separate guidance at http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/):** You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. Therefore, you need to use effective birth control while on this study. [As appropriate, specify what methods of birth control are required or acceptable and discuss how long to use them.]
* **Unknown Risks to Women of Child Bearing Potential and Pregnant Women (See separate guidance at http://research.ucdavis.edu/policiescompliance/irb-admin/researchers/irb-forms/):** The effects of XXX on fertility or a fetus are not known. For this reason, if you believe that you are pregnant or have a chance of becoming pregnant you should not participate in this study. A [blood / urine] pregnancy test will be performed before the start of study procedures. If you are pregnant, you will not be allowed to participate in the study. If you do participate in this study, you must use a medically effective form of birth control before entering the study, while participating in the study, and for at least XXX after stopping the study. If you become pregnant during the study, tell the researchers right away.
* **Unknown risks:** For studies involving investigational agents, or experimental doses or combinations of drugs and/or treatments, tell subjects that there may be risks associated with the drug/treatment that are as yet unknown , but that the researcher will advise them if any new information becomes available that might affect their desire to participate in the study.
* **Statement about treating side effects:** The researchers will observe you carefully for any harmful side effects. Although the experimental drug/device has been well- tested in laboratory and animal studies, the side effects in people are not completely known at this time. You will be followed closely by the study doctor for the entire time you are a part of this study. If you experience any side effects from the study, the researchers will provide you with the treatment that has the best chance of taking care of the side effects. If you experience any side effects related to the study drug/device that continue at the end of study, we will continue to follow-up with you until these effects stabilize or resolve.
* **Risks associated with randomization:** You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study groups(s), or standard treatments available for your condition.
* **Risks associated with withdrawing from current medication (washout period**): During this study the medication you normally use for your condition will/may be stopped for up to [XX days/weeks/months]. You will/may receive no medication, or medication at a dose which may not help your condition. As a result, you will/may have an increase in symptoms including XX.
* **Placebo risks:** During this study there is a XX chance that you will receive a placebo. This could lengthen the amount of time before you receive a treatment that may be effective. During this time you may experience worsening of your condition, including increased symptoms such as XX. The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.
* **HIV testing risks**: Being tested for HIV can make you feel nervous or anxious about the test results. A positive test indicates that you are infected with the HIV virus, but no one knows for certain when, if ever, you will get AIDS or a related condition. Receiving positive results may make you very upset. If other people learn about your positive test results, there might be a risk that you could be treated unfairly or badly, and even have trouble obtaining insurance or employment. To the extent permitted by law, the researchers will keep your test results confidential and will not release them to anyone without your written permission. If you test positive, California law requires health care providers and clinical laboratories to report the HIV test results with your personal identifying information to the local health department.
* **Exercise testing risks:** The exercise test(s) may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs.
* **Psychological risks:** Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.
* **Unknown Risks:** The experimental drug may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.
* **Skin Biopsy Risks:** During this study, one or more skin biopsies may be taken from you as described above. The size of these biopsies will be \_\_\_\_\_ inches in diameter. Obtaining a skin biopsy may cause some discomfort and is similar to having your blood drawn. In addition to discomfort, additional risks of skin biopsies include infection at the biopsy site. After the skin biopsy is taken, it will be important for you to keep the area clean and covered with a bandage until it is healed to prevent infection. Unlike a blood draw, the time for a biopsy site to heal is often longer.