CT SERVICE CENTER SOP #301
Consent Forms – CT Exams Standard Language

Responsible Committee:	Effective From:	Last Approved:	Next Approval:
Safety	January 1, 2026	N/A	December 1, 2026

1. Purpose

This standard operating procedure (SOP) describes the required verbiage needed in the consent when performing research CT scans that are not being done for clinical treatment purposes.

2. Scope

This process applies to research CT scans that would not be done for standard medical care.

3. Instructions and Procedures - Risks: CT imaging and incidental findings

3.1 When to use the incidental findings text in the consent form?

Any CT exam for which a diagnostic report will not be generated requires incidental finding text in the consent form. If a radiologist will not be reviewing the images, this must also be stated. N.B. Please also see SOP XXX regarding how to document incidental findings on exams which do not receive a diagnostic report.

Incidental Findings Consent Language

This CT is not a clinical scan. It is possible that during the research study, the Investigator may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel, and the PI will inform you if the finding requires any further action on your part. These possible findings may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

No Radiologist Reading/Interpretation

The CT performed under this protocol is not for medical purposes, and the images are not planned to be interpreted by a Radiologist.

3.2 When to use the contrast text in the consent form?

If the subject will be receiving a CT contrast agent when they would not per standard of care, contrast text should be included in the consent form. Below is text for the most used agent at the University of Pennsylvania. If a different contrast agent is to be used, this text will need to be appropriately updated. If the patient is pregnant, additional text must be included.

IV Contrast Risk Language

Part of your CT study will require the injection of an iodinated contrast agent into your blood stream. An intravenous line may need to be placed. There is a possibility that multiple needle sticks will be necessary to ensure proper intravenous line placement. A small amount of pain or bruise may

occur with intravenous catheter (IV) placement and there is a small risk of infection at the injection site. There is a rare possibility that you could have an adverse reaction to the contrast agent such as rash, hives, itching, mild headache and nausea. Approximately 95% of CT contrast reactions are mild to moderate in degree and most resolve without treatment. However, life-threatening reactions and fatalities, mostly of cardiovascular origin, have occurred. People with heart disease, kidney disease, or allergies are more likely to have severe reactions to contrast agents. If you have a history of heart disease, kidney disease, or allergies please inform the study staff.

Common effects of iodinated IV contrast agents are:

- Feelings of overall warmth, especially in the bladder area after injection
- A metallic taste during the injection
- Warmth, burning sensation or momentary pain at the injection site during contrast injection
- Less common are nausea, vomiting, headache, hives and itching
- Rare, but serious reactions are rapid heartbeat, changes in blood pressure, heart attack, kidney failure, pulmonary edema, serious life-threatening allergic reaction.

[The table below may be also included for clarity]

Risks of CT intravenous contrast reactions		
Likely	**Less Likely**	**Rare, but serious**
Feelings of overall warmth especially in the bladder area after injection	Nausea, vomiting	Tachycardia, hypotension, hypertension
A metallic taste during the injection	Headache	Heart attack, kidney failure, pulmonary edema
Warmth, burning sensation, or momentary pain during the contrast injection at the injection site can occur	Hives and itching	Serious, life-threatening allergic reaction

Pregnancy

Diagnostic iodinated contrast media have been shown to cross the human placenta and enter the fetus when given in usual clinical doses. In-vivo tests in animals have shown no evidence of either mutagenic or teratogenic effects with low-osmolality contrast media (LOCM). No well-controlled studies of the teratogenic effects of these media in pregnant women have been performed.