I would like to recruit more subjects and want to increase the potential compensation amount for my study. Can I mention the amount that subjects will be paid in my study advertisement?

Yes, the compensation amount can be stated. However, it should not be put in large type or emphasized in any way.

Advertisements submitted to the University of Chicago BSD/UCMC Institutional Review Board should include:

- The purpose of the research
- Summary of eligibility criteria
- Estimated time commitment
- Name of the PI
- Location of the research
- Contact information
- Identification as advertisement for "research"

but

- NOT Promise free medical care or free medications
- NOT Emphasize payment or amount to be paid by such means as larger or bold type
- NOT Name unapproved study drugs by name
- NOT Contain therapeutic claims

Please also see the FDA Information Sheet on “Recruiting Study Subjects” at http://www.fda.gov

I would like to recruit subjects through a temporary employment agency. Will this be acceptable to the IRB?

Several IRBs have been asked to review protocols that propose to recruit subjects though temporary employment agencies. Per University Research Administration, this method of recruitment is inherently problematic. Temporary employment agencies are intended for employment opportunities, while participation as a human volunteer in a research project is NOT considered an employment opportunity. Employment agencies have access to disadvantaged populations, who may feel compelled to accept assignments to research projects either for the financial incentive alone or in order to maintain their relationship with a temporary employment agency to secure future placements. Thus, temporary employment agencies should not be used as a recruitment resource for research projects.

My sponsor is requesting that certain language be put in the consent form regarding research-related injury. Now the IRB is asking me to remove this language. Why?

Research-related injury language is generally negotiated with the sponsor during the contract negotiations. The University of Chicago provides consent form language concerning research-related injury that is expected to be used unless the IRB is notified otherwise by the U of C contract team.

For more information, please see the above FAQ, "Does our site have a policy on research-related injury."

When is it necessary to re-consent subjects?

Over the course of conducting a research study, investigators may find that changes to the protocol are indicated, whether due to newly discovered risks, a change in protocol design, or some other factor. Whatever the change, it may require re-obtaining consent from previously consented subjects in order to continue their participation in the study.

The need to re-consent derives from the federal regulations governing research, which require that subjects be informed of significant new information that may affect their continued willingness to participate. This new information may include the following:

- increase in study length
- increased number of study visits
- a change in study venue(s)
- increased risks to subjects
- decreased benefit to subjects revealed than previously believed to be present

Therefore, investigators should evaluate the need for re-consenting previously enrolled subjects when such types of changes occur, or other changes that may affect willingness to participate.

In addition, if a study is terminated or expires while subjects are still on study, subjects will need to be informed of the study termination or expiration and study procedures must be halted. Study procedures may only continue on a terminated study if immediate withholding of study drug or procedures from subjects would affect their health or welfare. In that case, the IRB must be kept informed of subjects' welfare and a new protocol submitted as soon as possible in order to keep subjects on study. In any case of study termination or expiration, if investigators wish to continue study procedures a new protocol and consent form will be required by the IRB. This new protocol and consent must be approved by the IRB and subjects should be re-consented using the new consent form version before they continue their participation.

The decision to re-consent subjects on an active protocol should be made by the principal investigator during the time of amendment submission. When amending the protocol to include the new information, the investigator will be asked to provide an assessment of whether re-consenting is required, and to submit a revised consent form as applicable. However, even if an investigator feels that re-consenting is not required, the IRB retains the final decision concerning re-consenting and may request that it be done if the IRB feels that subjects' decisions regarding participation may be affected by this new information.

In a related situation, investigators with protocols involving the use of proxy consent may also need to obtain the consent of previously-consented subjects. In this case, if and when subjects for whom someone else has given proxy consent regain the ability to consent for themselves, the investigator must obtain the consent of that subject directly in order for the subject to continue on the study. While not technically "re-consenting," as the subject did not originally participate in a consent process, this circumstance does require that a subject who had previously been enrolled may only continue participation after another consent process has taken place.

What consent elements are required for an addendum consent form? What elements are required for an "optional" consent form?

Optional consent forms should contain all required elements of informed consent. Since the decision to participate is optional and is made outside the decision to participate in the "main" study, it is an independent consent form and process and thus all required elements should be included.

Addendum consent forms that are used to provide new information about an existing agreement to consent could contain sections with text to "refer to main consent" or similar. For example, a consent form for dosing beyond disease progression is an agreement to continue participation in the main study despite new information (i.e. progression of disease). Therefore, it could refer a subject back to the main consent form for information such as the dosing schedule or confidentiality protections, as long as those were not altered by the disease progression. Any new information regarding risks or procedures should be clearly described in the addendum.

For any type of consent, the AURA submission form should be clear about when each consent process will occur. For example, consent to dosing beyond disease progression would not be expected to occur until a subject had actually progressed, and therefore it would be expected that the consent discussion would occur at a later time point than the main consent discussion. It would also be expected that there would be some kind of "refresher" discussion and/or reference to the main consent form contents when discussing the agreement to continue on study beyond disease progression. In other words, the addendum consent form would be used in conjunction with the main consent form that had already been signed.

How do I enroll a subject who does not speak English?

For research in which investigators expect to enroll non-English speaking subjects, a consent form translated into the native language of the subjects to be enrolled must be provided to the IRB with the original submission or, if this study population is being added, with the amendment. A certified translator should perform the translation and proof of certification should be provided to the IRB along with the translated consent form.

Any recruitment materials (flyers, radio advertisements, etc.) that have been translated should also be provided to the IRB. In addition, investigators should translate all study materials that

will be distributed to non-English-speaking subjects, such as surveys or questionnaires, and submit these to the IRB when the translated consent is submitted.

The translated documents must be approved by the IRB before non-English speaking subjects can be enrolled into the study.

Note that the exclusion criteria in certain protocols may specifically exclude non-English-speaking subjects from participating. Check your full written protocol for inclusion/ exclusion criteria before enrolling non-English speaking subjects.

Please ensure that a person who speaks the language of the subject to be enrolled conducts the consent discussion and is available throughout the study, as applicable.

What if investigators encounter a potential subject who is Non-English-speaking, but do not already have a translated consent?

In some cases, a non-English speaker may be eligible for a study for which there is no translated consent document, and for which the study investigators could not have foreseen enrollment of a potential subject who speaks that language. In this case, investigators may choose to enroll the potential subject using a "short form" consent that has been translated into the subject's native language.

The consent process must involve a translator who can verbally translate the information in the full written informed consent into the subject's native language. A witness to the translation must also sign the consent form; the translator may function as the witness.

If PHI will be used and/or disclosed as part of the research, the subject should also sign a HIPAA authorization for this use/disclosure written in a language understandable to the subject. Please contact the HIPAA Program Office for more information on translated HIPAA authorization forms.

A general authorization in Spanish for use/disclosure of PHI is available on that website.

Like the translated full written consent document, the IRB must approve the translated short form consent prior to its use. However, expedited review of an amendment to approve a translated short form consent is possible if the IRB has previously approved both the protocol in question and the protocol's full English-language informed consent document.

The IRB has approved a short form consent document and has had this consent translated into several languages. Several translations have also been provided by the Cancer Clinical Trials Office (CCTO) (thanks to the CCTO for allowing the IRB office to share these). For the languages listed below, please contact the IRB for a copy of the translated document when submitting an amendment to use the short form consent.

For any language not listed below, the investigator is responsible for obtaining a certified translation. The English language short form is available below for download:

Short form consent (English) - study was approved under 1991 Common Rule requirements
Short form consent (English) - study was approved under 2018 Common Rule requirements

1991 Common Rule versions available from the IRB office include Spanish, Arabic, Bosnian-Serbian, Bulgarian, Cantonese, Greek, Hebrew, Hindi, Korean, Macedonian, Mandarin, Polish, Portuguese, Romanian, Russian

How do I enroll a subject who does not read or write?

A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document.

If you wish to enroll a person who can understand and comprehend spoken English, but is physically unable to talk or write, or a person who cannot read the consent form (e.g. illiterate persons), you may do so as long as the person is competent and able to indicate approval or disapproval by other means. The person must:

1) retain the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and
2) be able to indicate approval or disapproval to study entry.

The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.

Note that for any study for which enrollment of illiterate persons is expected, this should be clearly indicated during the time of original protocol submission. If an approved study now wishes to enroll an illiterate person or persons, an amendment will need to be submitted to request approval for a change in eligibility criteria, describe the consent process for this individual or individuals, and describe how it will differ from the approved consent process.

Does the IRB have sample consent form language for protocol-required birth control?

When a protocol requires "extremely" effective birth control methods (defined as a failure rate of <1% per year when used consistently and correctly), the research consent form should provide specific examples for potential subjects.

Namely, the following methods have 1% or less pregnancy rate:

- Blocked fallopian tubes tubal ligation (commonly referred to as having your "tubes tied"), salpingectomies (having one or both of your fallopian tubes removed), or essure (a procedure to block the fallopian tubes, which is no longer being performed)
- Male partner vasectomy
- Birth control implant (nexplanon is the current version)
- Intrauterine devices (IUD)

Total abstinence or same sex intercourse is 100% effective at preventing pregnancy.

The above language can be used or modified for use in the consent form.