Recruitment

Initial Contact with Potential Participants

- When there has been no previous contact with a potential participant, care must be taken to ensure that the potential participant understands how the researcher acquired private information about them, and that the information was obtained in a legitimate manner. For example, if the participant was referred to the researcher by the individual's physician or other treating health care professional, the researcher can cite that referral as a reason for the contact.

- Extreme caution should be exercised when potential participants are identified through chart reviews or through a Waiver of HIPAA Authorization for recruitment, as these avenues to PHI are less familiar to participants, and can lead to complaints to the Privacy Office when misconstrued as illegal use of PHI. In these cases, the researcher might first consider sending a letter to participants, signed by a health care provider or hospital department that would be recognizable to the potential participant, and providing a telephone number or other means that the potential subject can use to verify that the study constitutes MD Anderson research.

The Principal Investigator must consider all the following elements when planning recruitment:

- Purposes of the research
- Inclusion/exclusion criteria
- Whether participants may be susceptible to coercion or undue influence
- Whether a population that stands no chance of benefiting is being selected to assume the risk
- Recruitment methods and materials
- Payment arrangements
- Research environment
- Timing of the consent process

Recruiting special subject populations

Vulnerable participants:

- Provide a rationale for involvement of vulnerable subjects, such as children, prisoners, pregnant women, economically and educationally disadvantaged, decisionally impaired, and homeless people, and
- Address why a less vulnerable population would not serve as well.

Children:

- Explain whether enrollment is limited to children. Research that limits enrollment to children is generally not appropriate unless
  - (i) the condition or disease is limited to children, or
  - (ii) the research seeks to obtain information on a test article or procedure that previously had been studied only in adults.

Members of minority groups:

- Explain whether the research holds out the prospect of benefit to individual subjects or the groups to which they belong, and
- How non-English speaking participants will be consented.

MD Anderson employees:

- Explain how they will be protected from coercion and undue influence, and
- What alternatives to participation exist?

Excluding women and certain other types of participants

Explain whether it is justified by:

- Physiology, e.g. treatment for prostate cancer;
- Cultural prohibitions, e.g. one-to-one interviews of women in a situation where that might be construed as morally unacceptable;
- Childbearing potential, when women are not able to use reliable birth control methods for religious or

other reasons and might have to be excluded from early Phase I studies of toxic chemical agents;
- Other reasons to be considered by the IRB.

Advertisements see MD Anderson Policy on Advertising and Recruiting for a Research Study - guidance Advertisements: Appropriate Language for Recruitment Material

Payment to participants

When proposing payment, there must be justification to:
- Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject;
- State the terms of the subject participation agreement and the amount of payment in the informed consent form; and
- Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the subject to volunteer for the research study.

Recruitment material to submit for IRB review

- ***Audio and video tape****:* The IRB may review and approve the wording prior to taping in order to preclude re-taping due to inappropriate wording, with expedited review of final broadcast-ready tape.
- ***Printed advertisement****:* The IRB will review the final copy to evaluate visual effects of materials.
- ***Telephone****:* The IRB will review the phone scripts to determine whether the information collected constitutes the minimum necessary to establish basic eligibility for the specific study.
- ***Internet and web postings****:* The IRB will review the final draft to evaluate wording and visual effects.
- ***Listings on clinicaltrials.gov*** and the ***MD Anderson Clinical Trials website*** do ***not*** require IRB review.

Not allowed

The following activities are examined carefully and generally not allowed:
- Payment *from* research participants
- Compensation for participation in the form of a coupon for a discount on the test article to be used after the product has been approved for marketing.
- Exculpatory language through which the participant or participant's LAR is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator , the sponsor, the institution or its agents from liability for negligence.

Resources

Federal Agency	• 45 CFR 46.111(a)(3); 45 CFR 46.116 • OHRP Guidance on Written IRB Procedures • OHRP Compliance Activities: Common Findings and Guidance #3, #45 and #65 21 CFR 50.20; 21 CFR 56.111(a)(3) • FDA Information Sheets: FAQs: Informed Consent Document Content, FAQs: IRB Organization, A Guide to Informed Consent, Recruiting Study Subjects, Payment to Research Subjects
MDACC HRPP	MD Anderson Policy on Advertising and Recruiting for a Research Study Guidance on Advertisements: Appropriate Language for Recruitment Material

Versions

Date	Version Number	Action	Initials	Description
11/1/2018	1	New	MT	Created new document