Protection of Human Subjects

Human subjects involvement and Characteristics

Proposed Involvement of Human Subjects

Describe characteristics of the subject population, number, age range and health status

Criteria for inclusion or exclusion

Sources of Materials

Describe data collected from human subjects

Who will have access to the private information

Which data is collected specifically for the research

Potential Risks

Describe risks to subjects

Recruitment and Informed Consent

Plans for recruitment of subject

Describe how consent will be sought

Protections Against Risk

Describe these.

Potential Benefits of the Proposed Research

Importance of the Knowledge gained

The proposed study will be performed using existent facilities in our interventional radiology suite and patients' imaging data. Following establishing technical necessities to perform optimal image registration in our interventional radiology suite we will transfer, register and evaluate images of patients who are having CT guided biopsy or ablation as a bystander. Clinical care of the patients will be carried out as normal by clinical team on duty and will not be effected from our study. Therefore, there is no potential risk for the patients involved, since there is no clinical decision made based on our study.
However, in a future phase, after evaluating the results of this pilot study, we will consider a prospective clinical trial to evaluate the value of image registration during CT guided biopsy and tumor ablations.

Why Risks are Reasonable
This proposal has no direct impact on the patients' treatment. The only risks for the

patients are related to the protection of subject's privacy and confidentiality. This aspect is further addressed.

Protection of Subject's Privacy and Confidentiality:
This study deals with processed existent medical imaging data at BWH.
Database Construction: A database and a "link table" will be set up with password protections. The data will undergo de-identification of subjects' information such as medical record number and other patient identifiable information. The full name and medical record number of each subject will be stored as meta data associated with each MRI scan in the link table. This will enable association with clinical data and tracking of serial follow-up. Important clinical characteristics such as birth data, and date of scan will be stored in a separate file with password restrictions.
Data Storage and Access: In compliance with the Harvard Faculty Policy on Integrity in Science (www.hms.harvard.edy/integrity/scientif.html), the primary data will be stored electronically in the Surgical Planning Laboratory, BWH, and preserved for the life of the laboratory. Access to all of this data will be restricted to protect privacy and confidentiality by password access to accounts on a UNIX computer system and network, and this study data will be accessible only to members of the research team listed on the IRB application.
Institutional Commitment: BWH, HMS is fully committed and in compliance with HIPPA regulations. Institution wide training of all members occurred by mid April 2003. All investigators have also undergone IRB training and a certification exam.