

THE UNIVERSITY OF ARIZONA HUMAN SUBJECTS PROTECTION PROGRAM

PROJECT APPROVAL FORM FOR SUBMISSION TO WESTERN IRB (WIRB)

PROJECT TITLE: _____

PROTOCOL NO.: _____

IDENTIFICATION OF PI(S)

Principal Investigator(s) and Degree(s): _____

Contact phone: _____

Email: _____

PROTOCOL INFORMATION

IND/IDE No.: _____

State where study records will be stored (Building/Room): _____

State where study drug(s) will be stored (Pharmacy or Building/Room): _____

ASSURANCES

I certify that the above cited project falls under the WIRB-UA contract in that it:

- Is a Phase I, II, or III trial; AND
- Will only enroll adults (defined as over the age of 18 in the state of Arizona); AND
- Is a multi-site study; AND
- Is industry-sponsored.

I certify that the all checked approvals from appropriate committees will be obtained prior to the initiation of research, including but not limited to:

_____ **Medical Radiation Safety Committee** for projects involving any radiation, MRI, or lasers;

_____ **Institutional Biosafety Committee** for projects involving the use of gene therapy, recombinant DNA, or DHHS select agents or toxins;

_____ **Scientific Review Committee** for all projects being conducted at the Arizona Cancer Center;

_____ **Conflict of Interest** Disclosure has been filed with the Vice President of Research Office

_____ **Other** (define):

I certify that no unspecified future research will be conducted on samples collected under the proposed research project. Research will be limited to the anatomical system, class of diseases, or drug/device being studied.

I certify that the research-related injury statement will not include exculpatory language, including any language regarding lack of compensation due to the subject failing to follow instructions.

I certify that all study staff will maintain active human subjects training approval throughout the life of the project.

I certify that I have identified all units that need to be prepared for their involvement in the research project (e.g. nursing, radiology, etc.) and the mechanism used to facilitate communication with those units.

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I certify that I have notified my Department Head and/or Dean of this project and that they concur with this project being conducted.

I certify that the original signed consent forms will be stored in the official departmental location as designated by the Department Head.

I certify that any recruitment or research that will be done outside of my home department/clinic will be done after obtaining written site authorization from a member of that unit with authoritative power to grant access.

I certify that no study procedures will take place at the Southern Arizona VA Health Care System (SAVAHCS) in accordance with VA regulations.

Note: Failure to adhere to the above statements may result in suspension of the research study and loss of WIRB use.

Principal Investigator Signature

Date

Department