Research Evaluation Form

SECTION 1: INFORMED CONSENT CHECKLIST

PROTOCOL #:_____ Final Yes □ No □ Date_____

INTRODUCTION	YES	NO	NA	Notes
Title	____	____	____	_____
Name of Investigators/Address/Tel. #	____	____	____	_____
Invitation to participate in a research study and why	____	____	____	_____
Evaluate study population vulnerability	____	____	____	_____
Pediatric/Assent	____	____	____	_____
NATURE/PURPOSE				
Clear explanation of the purpose (layman's term)	____	____	____	_____
STUDY DESIGN				
# of subjects/sites	____	____	____	_____
Duration of the study	____	____	____	_____
Double Blind/Information available	____	____	____	_____
All procedures, placebo, randomization, dose escalation	____	____	____	_____
Blood Sampling	____	____	____	_____
Restrictions	____	____	____	_____
RISK AND DISCOMFORTS				
Foreseeable risks and discomforts	____	____	____	_____
Placebo/ out of control/worsening of disease/Precautions	____	____	____	_____
Risks to Newborn	____	____	____	_____
Potential for interaction/addiction/allergy	____	____	____	_____
Unknown /Unforeseeable risks/Reporting New Risks	____	____	____	_____
BENEFIT				
Description of benefits	____	____	____	_____
ALTERNATIVE PROCEDURES				
Disclosure of alternative treatments, procedures	____	____	____	_____
VOLUNTARY PARTICIPATION/WITHDRAWAL				
May withdraw consent even after signing form (voluntary)	____	____	____	_____
will not go against future care/no penalty or loss of benefits	____	____	____	_____
Involuntary withdraw	____	____	____	_____
PAYMENT Include payment & breakdown	____	____	____	_____
COMPENSATION/COST FOR PARTICIPATION				
Compensation for injury	____	____	____	_____
Do not waive legal rights	____	____	____	_____
Any additional cost for participation	____	____	____	_____
CONFIDENTIALITY				
IIRB, Sponsor & agents, FDA, etc. access	____	____	____	_____
Absolute confidentiality not guaranteed	____	____	____	_____
Use of initials for publication	____	____	____	_____
No Expiration/50 years [CA/WA]	____	____	____	_____
HIPPA font size [CA]	____	____	____	_____
revoke in writing/access to information	____	____	____	_____
QUESTIONS/CLOSING				
Who to contact in case of emergency/questions/24 hr	____	____	____	_____
IIRB for rights as a study participant	____	____	____	_____
Required signatures/competency to consent	____	____	____	_____

Investigators Brochure Date: _____ SAE Reports: _____ Package Insert: _____

Genetic ICF Yes □ No □ Photographic ICF Yes □ No □ Other ICF/Addendum Yes □ No □

SECTION 2: RISK CHECKLIST

Risks to the unborn:

- ☐ Males only no known fetal risks
- ☐ Males only known fetal risks (address in ICF)

- ☐ Post Menopausal Women study - Protocol requires medical documentation of PM status/Surgical Sterilization status
- ☐ Post Menopausal Women study - Protocol does not require medical documentation of PM status/Surgical Sterilization status **Note in approval letter required!**

- ☐ Includes WOCBP and Protocol describes BC
- ☐ Includes WOCBP but Protocol does not describe BC: **Note in ICF and approval letter required!**

Pregnancy Testing

- ☐ Pregnancy testing for all female at least prior to dosing
- ☐ Pregnancy testing for WOCBP only at least prior to dosing – PM/SS with medical documentation
- ☐ **Note in approval letter required because protocol does not require medical documentation of** PM status/Surgical Sterilization status and does not require pregnancy testing

Drug Alcohol screening prior to dosing?

At least prior to dosing: ☐ Drug screening ☐ alcohol screening

☐ No drug/alcohol screening **Note in approval letter required!**

Committee Findings: _____

_____

_____

Risk-Benefit Assessment

What is the benefit of the research? _____

What is the nature of the risks/were risks minimized? _____

_____

_____

Type of subject vulnerability/appropriate safeguards? _____

_____

_____

Pediatrics being enrolled? ☐ No ☐ Yes* * If yes complete Section 3 of this form ,if no leave Section 3 blank

Blood Volume: ☐ w/in Blood Bank Standard ☐ documentation of volume w/in protocol ☐ see notes

Overall conclusion regarding study merit: ☐ Justified ☐ Requires Additional Information

STATUS ☐ Approved ☐ Tabled

Length of Approval: ☐ 12 months ☐ 6 months ☐ other Justification_____

_____

Committee Findings: _____

_____

_____

Signature_____

Section 3: REVIEW OF RESEARCH THAT INCLUDES MINORS*

*States with exception to the 18 years of age for emancipation for research participation:

*IIRB does not approve research that involve minors that are the ward of the State or any other agency, institution or entity

APPROVAL ELEMENTS

Research involves:

- ☐ Neonates: (birth to 1 month)
- ☐ Infants (1 month to 2 years)
- ☐ Children (2 years to 12 years)
- ☐ Adolescent (12 years to 17 years)

CATEGORY OF RESEARCH

- ☐ Research that involves no more than minimal risk
- ☐ Research involves more than minimal risk but provides direct benefit to the child (the risk must be justified by the anticipated benefit and be at least as favorable as the alternative treatment).
- ☐ Research involves more than minimal risk, does not provide direct benefit to the child, but is likely to yield generalizable knowledge about minor's disorder or condition
- ☐ Research involves more than minimal risk, does not provide direct benefit to the child, but is likely to yield generalizable knowledge about a disorder or condition (i.e., Phase I research)

SIGNATURE REQUIREMENTS

- ☐ one parent (or legally authorized individual)
- ☐ both parents (or legally authorized individual) or documentation of sole custody
- ☐ Assent required: ☐ not required:_____

FINDINGS

- ☐ Risks have been minimized
- ☐ Research not justified
- ☐ Placebo design justified ☐ Not Applicable
- ☐ generalizable knowledge anticipated to be significant
- ☐ Approval of research not justified based on available documentation: _____

_____

_____

INFORMED CONSENT REQUIREMENTS

- ☐ Assent documented: ☐ not required: _____
- ☐ Introduction Statement (informing minor and parent that both must sign icf)
  ☐ not required:_____
- ☐ PI can withdraw the minor if the minor indicates that they do not wish to be in the study or by display or behavior or verbalization (particularly in research involving young children)
  ☐ not required: _____
- ☐ Signature lines present for Parent/Legal Guardian/Assent