



Preclinical Request Form

Please email this form to mike.mcgarry@medelis.com and droach@medelis.com.

Requesting Corporation	
Responsible PI	
Role in Organization	
Contact information	

Status of Investigation

Exploratory
Toxicity
Tumor Sensitivity

Proof of Principle
Pharmacokinetics
Tumor Uptake

Preclinical Efficacy
Delivery Options
GLP Required

Funding Source

Private
Corporate
Other non-government:

NIH
USDA

Protocol

Animal species requested	
Age	
Sex	
Strain	
Health Status	
Estimated number required	
Estimated duration of study	

Please attach protocol details, schedule and dose regimen, if known.

If protocol is to be developed, provide as much information as possible:

1. What therapeutic agent will be administered? Will it be toxic, aqueous, saline, solvent, sterile, hazard, isotope, labile, protein, liposomes, slow release particles, etc.

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2. Will it be viscous, thermolabile, a suspension, need to be kept on ice until injected?
3. Are the route and site determined? Intratumoral, systemic, intravascular only;
4. Will there be multiple injections? What schedule is envisioned? What volume is required?
5. Is the desired tumor cell line already determined and available, or will Medelis Preclinical Resources acquire it?
6. Will the therapy produce hazardous exposures to the animals or technical/husbandry staff?
BMBL Animal Safety Level?

Endpoints – please describe:

1. Survival (moribund animals are sacrificed)
2. Tumor dimensions – periodicity of determination
 - a. Two dimensions – largest diameter and perpendicular diameter
 - i. Formula for volume calculation
 - ii. Area of tumor
 - b. Three dimension estimates
 - c. Cell counts
 - i. Peripheral blood - serial counts from tail blood
 - ii. Ascites cell count
 - iii. Tumor cell count
 - d. Terminal, excised tumor weight
 - i. Other organ terminal weights
3. Periodic animal weights
4. Serial blood samples with serum preparation, CBC, other chemistries or serologies
5. Terminal organ or tumor histology
6. Other parameters of interest

Please provide your protocol schedule and treatment regimen in available:

1. Route and frequency of test agent
2. Positive control and vehicle control
3. Number per group; repeat schedule
4. Agent preparation at test site (solution, dilution, etc.)
5. Determination for onset of Rx:
 - a. Time after tumor cell inoculation
 - i. Number of viable cells to be delivered
 - ii. In vivo passage generation
6. Standard tumor size
7. Other