

TUMOR PRODUCTION GUIDELINES

If you are conducting tumor production studies in animals, all of the following issues should be addressed in the narrative section of the animal use protocol. NOTE: It is not acceptable to just answer the questions below, please provide this information within a few paragraphs describing the tumor production procedures.

1. Please state the source of the cells, tissues or cell cultures to be used.¹
 - a. If from human tissues, identify the source. Discuss what precautions will be taken and/or tests performed to insure that the human tissues do not contain human pathogens [e.g. *Hepatitis B Virus (HBV)*, *Hepatitis C Virus (HCV)*, *Human Immunodeficiency Virus (HIV)*, etc.] that could pose a hazard to animal care and/or research personnel. Confirm that Animal Biosafety Level 2 standards will be applied and adhered to with their use. Confirm that all staff have taken the Bloodborne Pathogen Training.² Discuss whether Institutional Review Board (IRB) approval has been given for this project.
 - b. If from cell cultures/lines, identify the source. All cell cultures / lines must be animal pathogen tested before the studies can begin. This is necessary to protect the animal colony from any unwanted pathogens as well as protect the study from any confounding effects due to a pathogen acquired from the cell culture / line. If animal pathogen testing has not been done, this service is provided by Veterinary Resources at no charge to the investigator.³
2. Provide detailed information regarding the preparation and implantation procedures including adherence to aseptic technique. Please refer to aseptic guidelines which are available on the ACUO Website. Discuss gauge of needle used. Discuss volume to be injected including concentration. Specify site of injection(s). If more than one site is being injected, please justify and discuss issues such as immobility, etc.
3. Provide detailed information regarding the follow-up and care post-implant. Address such issues as parameters monitored (i.e. tumor size, weight, hydration, ruffled fur, immobility, etc), frequency of observation, identify individual(s) responsible for observation, etc.
4. Discuss how long the animals will be exposed to the tumor (or the maximum time for the tumor to establish). Discuss whether the cells metastasize. Is there any ulceration expected to occur from the presence of the tumor?
5. Discuss what criteria will be used to evaluate when the animals should be euthanized earlier than the defined time point. Please refer to endpoint guidelines available on the ACUO Website. Please note that current guidelines state the tumor burden cannot exceed 10% of the animals' normal body weight.

NOTES: 1) ATCC does not provide human or animal pathogen testing.

2) Investigators and research staff handling human tissues, cells, or cultures are to assume that they contain bloodborne pathogens. Animal Biosafety Level 2 standards must be applied and adhered to with their use. All staff are required to take the [Bloodborne Pathogen Training](#) offered by Environmental Health and Safety (EHS). Please note it is the investigator's responsibility to inform all research staff of the possible risks associated with handling human tissues, cells, or cultures, and to assure this training has been completed. A reference article relative to the risks associated with human xenograft transplantation in animal research is located on the ACUO Website under Tumor Production Guidelines.

3) Animal pathogen testing is routinely required every 3 years to assure that testing has been performed for all potential pathogens. (*A cell line tested 2 – 3 years ago for the presence of animal pathogens may not have included the currently applicable pathogens and/or introduction of pathogen by animal passage.*)

4) Studies involving the use of pathogens, potentially pathogenic microorganisms, recombinant DNA molecules, or select agents must be registered with UMB Environmental Health and Safety (EHS) Institutional Biosafety Committee. Please contact EHS and forward a copy of their final approval for the protocol file. IACUC approval will not be granted until EHS approval has been obtained.