

Guidance for Completing the 'Application
for Initial & *De Novo* IACUC Review'

Guidance for Completing the 'Application

I.

K. Special Concerns or Requirements of the Study

Key Considerations / Best Practices / Notes

Departures from the Guide

If a departure from the recommendations of the _____ is required for the study, a scientific justification must be provided.

Field Studies

consideration if the activities impact the animals or the environment.

Appendix A

Original version of an example lay summary *NOT* written in plain language understandable to a non-scientist:

In human patients, breast cancer metastasis to bone induces severe pain. This pain is not well modulated by standard opiates. Cannabinoids have been used as homeopathic pain remedies for quite some time across many cultures but have not been well studied in controlled environments. This is no doubt partially due to legal concerns with cannabinoid use. In our studies we target cannabinoid receptor 2 specifically, which is predominantly expressed in immune cells and does not elicit psychotropic effects. Our preliminary data indicates that cannabinoid receptor 2 compounds may be effective in alleviating breast cancer induced bone pain. Here, we are proposing to evaluate the pain efficacy of our novel, experimental cannabinoid receptor 2 compounds by utilizing a direct to bone breast cancer metastasis model. This model incorporates murine breast cancer cells directly into the intramedullary space in one femur of Balb/C mice. Because the cells are sealed into the bone, complicating and life shortening factors such as extraneous metastasis to lung or brain can be avoided. This also allows us to study the mechanism of the cannabinoid receptor 2 compounds in the bone microenvironment. We consider the ability of cannabinoids to positively modify bone structural changes induced by tumor growth to be a fortunate effect- thus we are able to target three separate physiological effects of breast tumor growth with one single compound: the rate of primary tumor growth, pain alleviation, and positive modification of the bone microenvironment.

[Total word count: 238]

Modified version of an example lay summary written in plain language understandable to a non-scientist:

Breast cancer metastasis (the development of secondary malignant growths at a distance from the primary site of cancer) can cause severe pain in human patients. Physicians have struggled to help patients of the disease moderate the pain because standard opiate treatments (e.g., fentanyl, oxycodone, morphine)

Appendix B

USDA Pain & Distress Categories

Category B	Category C	Category D	Category E
Animals being bred or held for use in research but have not been subjected to any experimental procedures yet	Procedures involving no more than momentary or slight pain or distress to animals and no use of pain-relieving drugs, or procedures involving no pain or distress to animals	Procedures involving pain or distress to animals are appropriately relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress	Procedures involving pain or distress or potential pain and distress to animals that are NOT relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress

