



January 04, 2019

(b) (6), (b) (7)(C), Principal Investigator

(b) (6),

(b) (7)

(C)

RE: NOTIFICATION OF IACUC APPROVAL: PROTOCOL AB10V

STUDY TITLE: Non-GLP Feasibility Study of the (b) (4)

(b) (6), (b) (7)

The procedures and the animals used in the pre-clinical research proposal referenced above ("the Protocol"); Study Code **AB10V** was reviewed and approved by the T3 Labs Institutional Animal Care and Use Committee (IACUC) and by Designated Member Review on January 04, 2019. In accordance with federal regulations, this letter shall serve as written notification of the determination of the IACUC.

This approval notification letter confirms the IACUC's permission to use ten (10) Calves for a study in a stress level D in accordance with the protocol.

This approval is in effect for (1) year and on January 04, 2020 the first annual renewal will occur on the above referenced protocol. Protocols are in effect for a three (3) year period and will terminate on the third annual renewal period. This protocol and all amendment(s) will expire on January 04, 2022.

Please contact me if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

JC/SK

(b) (6), (b) (7)(C)

T3 Labs Study Code: AB10V

Sponsor Study Code: (b) (4)

Is any exemption requested? (Y/N) If Y, please provide Duration and Justification below.		Y
Requested exemption from social housing (Check if needed post operatively)		<input checked="" type="checkbox"/>
Requested exemption from environmental enrichment devices		<input type="checkbox"/>
Requested exemption from exercise		<input checked="" type="checkbox"/>
Requested exemption from normal diet and/or water provisions		<input type="checkbox"/>
Requested exemption from standard caging		<input checked="" type="checkbox"/>
Requested exemption for restraint:		<input checked="" type="checkbox"/>
Duration and Description of Exemption(s):	<ul style="list-style-type: none"> Post operatively, the animals will be individually housed. The animals will be housed in an approximately 3' X 6' enclosure and the animal's head will need to be tethered/restrained with a loose rope to the front of the enclosure. During this time, the animals will be under 24-hour surveillance to prevent damage and entanglement. Animals will be unable to get adequate exercise during the period of restraint. 	
Justification for Exemption(s):	<p>Post operatively, the calves will be connected to the (b) (4) at all times via an externalized circuitry of tubing. It is important that the calf does not get entangled in this tubing or chew the tubing running along its back as that would lead to catastrophic loss of blood, injury and damage to the test article. Hence, individually housing with restraint in a smaller enclosure is necessary in order to prevent chewing, fighting, and large movements that would lead to entanglement. The calf would have enough space to stand up, sit or lay down comfortably. A simple tensioning device may be used to suspend blood tubing off of the animals' backs. T3 Labs has several years of experience running calf studies in these exact stanchioned pens and all measures will be taken to ensure that the animal is comfortable and not in any undue pain or distress.</p> <p>During the quarantine and acclimation period, the calves may be conditioned by tethering them or lead or rope training them for up to an hour each day to get them accustomed to the prolonged tethering, per veterinary discretion as needed. Per the vendor, the calves are already accustomed to wearing a halter and walking with a lead rope.</p>	

10.4 Type of surgical procedures

Survival	<input checked="" type="checkbox"/>
Acute	<input type="checkbox"/>



March 25, 2019

(b) (6), (b) (7)(C) Principal Investigator

(b) (6),

(b) (7)

(C)

RE: NOTIFICATION OF IACUC APPROVAL: PROTOCOL GT27F

STUDY TITLE: Integration of the Residual Limb with Prostheses (b) (4)

(b) (4)

(b) (6), (b) (7)

The procedures and the animals used in the pre-clinical research proposal referenced above ("the Protocol"); Study Code **GT27F** was reviewed and approved by the T3 Labs Institutional Animal Care and Use Committee (IACUC) and by Designated Member Review on March 25, 2019. In accordance with federal regulations, this letter shall serve as written notification of the determination of the IACUC.

This approval notification letter confirms the IACUC's permission to use (b) (4) for a study in a stress level D in accordance with the protocol.

This approval is in effect for (1) year and on March 25, 2020 the first annual renewal will occur on the above referenced protocol. Protocols are in effect for a three (3) year period and will terminate on the third annual renewal period. This protocol and all amendment(s) will expire on March 25, 2022.

Please contact me if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

JC/SK

(b) (6), (b) (7)(C)

T3 Labs Study Code: GT27F

Sponsor Study Code: N/A

Is any exemption requested? (Y/N) If Y, please provide Duration and Justification below.		Y
Requested exemption from social housing (Check if needed post operatively)		<input checked="" type="checkbox"/>
Requested exemption from environmental enrichment devices		<input type="checkbox"/>
Requested exemption from exercise		<input type="checkbox"/>
Requested exemption from normal diet and/or water provisions		<input checked="" type="checkbox"/>
Requested exemption from standard caging		<input checked="" type="checkbox"/>
Requested exemption for restraint:		<input type="checkbox"/>
Duration and Description of Exemption(s):	1) Animals are to be single housed for the duration of the study. 2) Animals will be fasted overnight on days prior to going to (b) (4) for gait training. 3) Post-operatively, the elevated perch will be removed. In addition, plexiglass may be installed on the inside of the cage at the discretion of the investigators.	
Justification for Exemption(s):	1) After the amputation surgery, animals will either be casted or have an exposed implant coming through the skin. Animals will be single-housed in order to decrease the risk of infection or any other adverse events related to the surgical procedure. 2) Animals will need to be fasted overnight prior to being transported to (b) (4) (b) so that food can be used as a reward for successful performance of the required behavior. Animals will be fed their daily ration of food during the training sessions. 3) The elevated perch will be removed and plexiglass may be installed to prevent the prosthetic from getting stuck in the cage. Other forms of enrichment will be provided daily including group play outside of the cage.	

10.4 Type of surgical procedures

Survival	<input checked="" type="checkbox"/>
Acute	<input type="checkbox"/>
Minor operative procedure DMR – any surgical intervention that does not penetrate and expose a body cavity and does not produce permanent impairment of physical or physiological function. Minor surgery does not expose a body cavity and causes little or no physical impairment (e.g., wound suturing, peripheral vessel cannulation, percutaneous biopsy, and most procedures routinely done on an outpatient basis in veterinary clinical practice). Animals undergoing a minor	<input checked="" type="checkbox"/>