Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity and Assurance
Arizona State University
[redacted]
Phone: [redacted] *FAX:* [redacted]

Animal Protocol Review

ASU Protocol Number: **17-1533R**
Protocol Title: **Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity**
Principal Investigator: [redacted]
Date of Action: **11/10/2016**

The animal protocol review was considered by the Committee and the following decisions were made:

The protocol was approved by Full Committee Review as modified.

If you have not already done so, documentation of Level III Training (i.e., procedure-specific training) will need to be provided to the IACUC office before participants can perform procedures independently. For more information on Level III requirements see https://researchintegrity.asu.edu/training/animals/levelthree.

Total # of Animals: **5**
Species: Cat **Pain Level: D**

Protocol Approval Period: **11/10/2016 – 11/9/2019**

Sponsor: [redacted]
ASU Proposal/Award #:
Title:

Signature: [redacted] Date: **11/10/2016**
IACUC Chair or Designee

Cc: IACUC Office
IACUC Chair

IACUC Use Only	**IACUC Protocol #:** 17-1533R
Date: 9/27/2061	☐ IBC ☐ RSC ☐ Chem

ANIMAL USE PROTOCOL
ARIZONA STATE UNIVERSITY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
(revised July 2015)

Read "Instructions for Submitting the ASU Animal Use Protocol" before completing. **Upon approval, this protocol will become a public record so follow instructions carefully.**

PROJECT/PROGRAM TITLE: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity

SPECIES REQUESTED: *Felis catus*

I. PERSONNEL INFORMATION

A. A single member of the university faculty and/or Principal Investigator (PI) is considered the responsible individual.

NAME: [redacted] TITLE: Associate Professor

AFFILIATION: School of Biological and Health Systems Engineering Office Phone # [redacted]

Cell Phone #: [redacted] E-Mail: [redacted]

B. Additional contact, if any, for IACUC business

NAME: [redacted] TITLE: Laboratory Coordinator

AFFILIATION: School of Biological and Health Systems Engineering Office Phone # [redacted]

Cell Phone #: [redacted] E-Mail: [redacted]

C. Protocol Type

☐ Non-funded research

☒ Grant / Contract

Granting Agency: [redacted] Deadline: 10/31/2017

Co-Investigator(s): [redacted]

Proposal Title: [redacted]

ASU Proposal or Award #: [redacted]

If, ASU proposal or award number is not provided, attach a copy of the complete proposal or grant document.

☐ Teaching - Course Number and Title:

D. Protocol Status:

New

Renewal—Previous Protocol #:

Revision—Previous Protocol #:

E. Do you plan to use Department of Animal Care & Technologies (DACT) personnel and resources? If yes, describe the support needed? (If this use is new or an expansion of previous use, contact the DACT well in advance of need). Yes, husbandry and care, provide environmental enrichment, surgical assistance and pre- and post-operative care.

II. PROJECT DESCRIPTION AND PROGRAM REQUIREMENTS

The Institutional Animal Care and Use Committee (IACUC) is composed of both active animal users and lay persons. Regardless of background, each member has a vote, so it is particularly important that the language of the application be understood by all. This applies to all sections of the application, but it is especially important that the goals and justifications of the proposed research be spelled out in the clearest possible terms. NOTE: Upon approval, this protocol will become a public record, so do not disclose proprietary information.

A. Provide a brief (300 words or less) synopsis in **NON-SCIENTIFIC TERMS** of proposed research.

The ability to chronically interact electrically with the nervous system is vital for the treatment of traumatic injuries and various neurological pathologies. Recording neural signals from the nervous system is being used to treat epilepsy and paralysis. Most of these treatments use a small number of relatively simple electrodes. While some of these treatments have been highly successful, improving and expanding treatments using electrical interfacing with the nervous system will require more complex electrode technology. Increasing the number of electrodes in a neural interface increases the amount of information that can be recorded from the nervous system. Increasing the surface area and density of the electrodes may increase the biocompatibility and longevity of the electrodes. Our goal is to understand the longevity, biocompatibility and efficacy of high-channel count neural interfaces for potential use in human neural clinical applications.

B. PLANNED USE OF ANIMALS. Begin with a clear **statement of purpose** and briefly provide **background** information and **references** to previous work (especially if this is a renewal protocol). Include a clear description of the **experimental design** for all animal experiments planned and explain **why** the experiments must be performed. It is critical that for each procedure you provide a detailed sequence of events that effectively describes what happens to the animals from acquisition to euthanasia (if applicable). As the focus of the IACUC protocol is on animal use, do not simply cut and paste research objective statements from grant proposals. Flow charts, diagrams or tables are strongly recommended for complicated experimental designs. State how the research is expected to benefit the human community, the animal community, and/or society as a whole. **Details regarding surgical procedures, drug treatments, and field techniques are not necessary, as they will be addressed later in the form.**

We will test the ability of electrode arrays to chronically record neural signals *in vivo*. We will examine both the biocompatibility and efficacy of the arrays modified with nanotechnology to increase their surface area. The quality of neural recordings will serve a measure of device efficacy. At the end of the experiments we will obtain histology from the array implantation site to measure biocompatibility. We will correlate the histological data and recording quality. We are requesting a total of 5 cats for this study. Three animals will be carried over from our previous protocol,

1. Training

Preconditioning the cats for experimentation

In order to obtain the best possible neural signals we will be performing the neural recordings while the cats are awake. The cats will be accustomed to resting in the experimental room through prolonged exposure and positive reinforcement prior to beginning experiments. If necessary a cat restraint bag, a zippered bag which encloses the cat's body and limbs but not the cat's head, will be employed. The cats will be pre-conditioned to the restraint bag by using an open restraint bag as bedding for the cat in its home cage and/or in the experimental room.

The cats will be group housed or pair housed based on the personalities of the individuals. The cages will be opened so the cats can roam around the room. They will have access to scratching posts and have hiding places around the room. This study does not require the animal to perform a task for a reward so all animals will have ad lib access to food and water.

2. Recording

We will record electrophysiological signals from the implanted electrode arrays for up to 60 minutes several times per week.

Some cats may not tolerate the slight weight of the recoding connector on their heads. For these animals we have several potential approaches. First, we will place the animal in the cat bag. In some cases this calms the animal down and allows the recording to continue. If the animal does not tolerate the cat bag we will use a mild sedative such as midazolam (0.05 - 0.3 mg/kg SC or IM) or acepromazine (0.02 – 0.03 mg/kg SC or IM) to calm the animal. If the animal is still resistant to the recording procedure we may utilize other sedatives or anesthetics such as Telazol, ketamine, or propofol. In the case of an animal requiring either sedation or anesthesia during experimental sessions, the experimental sessions will be separated by at least three days.

3. Microstimulation

Microstimulation will be performed while the feline is anesthetized with an appropriate anesthetic (e.g., Telazol, ketamine, propofol) in order to prevent spontaneous movement and allow fine-wire EMG recordings. Constant current stimulation will be varied from 0-1.5 mA. Trains of 25 biphasic pulses, at pulse durations of 0-500 ms will be applied to all electrodes of the array in order to determine the amplitude of current required to evoke an EMG response. EMG responses will be recorded at 5 kS/sec using sterile, clinical fine-wire electrodes placed in the hind limb muscles. These sessions will occur at least 3 days apart, but will most likely be done once a week to once every 2 weeks and are expected to take one to two hours. In preparation for anesthesia the animal will be briefly fasted for ~3 hours beginning the morning of the procedure (prior to their AM feeding) and will be offered ad lib access to food once awake and recovered.

The general overall timeline of events from acquisition to training is shown in the table below:

Estimated duration (in months)	Action
0.5-1	Quarantine
1	Preconditioning
6	Recording/Stimulation

The timeline above reflects the estimated duration of events; actual duration may vary.
The goal of the study is to determine the longevity of the electrode arrays *in vivo*. The endpoint of the study will be determined by when the electrode arrays no longer function or we achieve 6 months of good performance. Animals may need to be kept available for any further experiments or controls required by reviewers for publication in the peer-reviewed scientific literature. This can be anywhere from 1 to 6 months after the completion of the experiments.

C. RATIONALE FOR INVOLVING ANIMALS AND THE APPROPRIATENESS OF THE **SPECIES AND NUMBER** USED. Keeping in mind the principles of the “3 R’s” (Refinement, Reduction, and Replacement), answer the following:

1. Why must live vertebrates be used in this study?
   We are developing neural prosthetics for implementations in human patients, so an accurate model of human neural systems is required. No lesser animal model, *in vitro* model, or computer simulation can replace pre-clinical testing.

2. Why are you using the requested species rather than other species?
   The major reason for using cats is that they are one of the lowest phylogenic species that is gyrencephalic and has a cortical thickness that is similar to humans. This allows for a more realistic extrapolation of biocompatibility to humans than performing the study in a lissencephalic species such as the rat. The size of the feline brain is the lower limit of what neurosurgeons feel is a reasonable model for human neurosurgery. We propose to use this species as opposed to the goat, sheep or pig due to the large body of literature on cortical function of the cat and our prior published studies using this model. Very little is known on cortical function of other large, gyrencephalic species and this would reduce our confidence in interpreting the results.

3. What is the rationale supporting the numbers of animals proposed? Typically, a power analysis should be performed to support the proposed sample sizes. A table depicting the number of animals to be used is required.
   The number of animals requested allows us to perform micro-stimulation using various parameters and obtain sufficient data to perform statistical analysis. The statistics on the micro-stimulation and electrophysiology will be based upon the number of electrodes, so will have very high statistical power. The statistics of the histological studies will be based on the number of animals. Three is an absolute minimum for statistical analysis, and typically the published literature has N of five or more in order to have sufficient power to yield significant results.

   Specifically, we will record electrophysiological signals on all electrodes in an array several times a week for the duration of the study. For electrophysiological analysis, N = 16 electrodes X 5 animals X 90 days = 7200. If this N is divided into four groups (control and three groups of different micro-stimulation parameters), then each group will have an N of 1800. On these datasets we will be analyzing the signal-to-noise ratio, the number and size of action potentials, and the power at different frequencies. The use of five animals, besides providing a large N for the electrophysiological analysis, also addresses the animal to animal variance in the histological analysis.

4. What refinements, if any, have been made to reduce the number of animals used and the potential detrimental effects on the study animals?
   All animals are routinely observed for any sign of pain or distress, and if any such signs are observed immediate action is taken to relieve the pain or distress. Every effort will be made to determine any source of distress to the animal and eliminate it. They will be provided with a variety of toys and other forms of environmental enrichment as well as the presence of compatible conspecifics when possible. Under no circumstances will analgesics or anesthetics be withheld from any animal. Lab staff will routinely socialize with the cats either in the colony room or the testing room.

III. EMERGENCY CONTACT

A. Who should be contacted in case of an animal emergency? **Note: This information will be redacted if this protocol is requested as a public document.**

Name:
Office Phone #:
Home Phone #:
Cell Phone #:

IV. DUPLICATION AND ALTERNATIVES

The Animal Welfare Act requires that you document your justifications with data from **two** or more sources. **One source** must **be a set of searches of a relevant database: name the database searched, the keyword and keyword combinations searched, the date the search was performed and the date range searched. The second source can be a set of searches of a second relevant database, or consultation with a laboratory animal science veterinarian, or courses/meetings/consultations with qualified personnel.** Sufficient documentation, such as the consultant's name and qualifications and the date and content of the consult, should be provided to the IACUC to demonstrate the expert's knowledge of the availability of alternatives in the specific field of study. Examples of appropriate databases to search include PUBMED, Web of Science, or Animal Welfare Information Center (AWIC – recommended for USDA-covered species; http://awic.nal.usda.gov/literature-searching-and-databases).

A. Provide the following details for the most recent literature search used to explore for duplicative research. (The literature search documents that the research will not unnecessarily duplicate previous research). **Teaching protocols do not need to conduct this search.**

Date that search was conducted (*Must be within 60 days of the IACUC review date*): 9/23/16
Database(s) used: Pubmed
Publication years covered by the search: 1975-2016
Keyword combinations used: multi-channel microelectrode array, micro-ecog electrode, chronic recording neural signals, micro-ECoG nanotechnology, microeclectrode array nanotechnology

B. Provide the following details for the most recent literature search used to explore for **alternatives to animal use** and **alternatives to painful procedures.** Alternatives should be considered for any aspect of the protocol that may cause more than momentary or slight pain or distress to the animal. Alternatives to be considered include those that would: 1) refine the procedure to minimize discomfort that the animal(s) may experience; 2) reduce the number of animals used overall; or 3) replace animals with non-animal alternatives (e.g., computer models or tissue culture). **All protocols (research and teaching) MUST conduct this search.**

Date that search was conducted (*Must be within 60 days of the IACUC review date*): 9/23/16
Database(s) used: Pubmed
Publication years covered by the search: 1979-2016
Keyword combinations used: Pain; Distress; Alternative, Anesthesia, Analgesia, Non-animal model, Feline, Cortical electrode array implantation, Micro-ECoG electrode implantation, Neural Prosthesis, Reduction, Refinement, and Replacement. These key words were searched in various combinations of 2 – 5 words.

C. Results of search for alternatives: Comment on the application(s) of any identified alternatives, including how these alternatives may be or may not be incorporated to modify a procedure to either lessen or eliminate potential pain and distress. **All protocols must complete this section. Protocols with USDA-covered species must describe how the literature search results relate to the literature searches for painful procedures and alternatives to animal use.** You must include sufficient information for the IACUC to determine that a reasonable, good faith effort was made to determine the availability of alternatives. If the search identified any alternative methods (ones that could be used to accomplish the goals of the animal use proposal), you must clearly explain and justify why this alternative cannot be used.
The searches listed above revealed no viable alternatives for the procedures used in the current research proposal, but reinforced our ideas of maximizing the animals' wellbeing through proper handing and environmental enrichment. Non-invasive methods of acquiring neural data and stimulating neural structures such as functional magnetic resonance and transcranial magnetic stimulation are not suitable for this study, as we are testing new array technologies. We are using state of the art technology to minimize the invasiveness of procedures. Searches did unveil some studies similar to ours, in which they used felines to test efficacy and biocompatibility of new array technologies.

D. Describe any other procedures (e.g., participation in meetings, review of journals) that are used to explore and evaluate alternatives:
The PI, Graduate Students and Lab Coordinator regularly attend national meetings and discuss with colleagues recent updates in technology and methodology for these experiments, as well as refinements in animal care and handling. All additionally remain up to date with the scientific literature on new and alternative procedures.

E. Does this research replicate previous work?

☒ No. Proceed to section **VI.**

☐ Yes. Explain why the replication is necessary:

☐ Not applicable. This is a teaching protocol.

V. CATEGORY OF PAIN OR DISTRESS

The USDA Regulations define a "painful or distressful procedure" as "any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied; that is, pain in excess of that caused by injections or other minor procedures." Using the table below, list all species of live vertebrate animals to be used in the proposed study and indicate the number of animals to be used under the appropriate USDA category. For an animal undergoing multiple procedures, list the animal under the highest level of pain expected for that animal.

Species	Number per USDA Category*				Total number of animals requested
	B	C	D	E	
Felis catus			5		5

*USDA PAIN CATEGORIES: (see http://researchintegrity.asu.edu/animals/forms for a more complete description of the below categories)

Classification B: Includes animals that are used solely for breeding (e.g., to produce experimental animals or to maintain experimental lines).

Classification C: Includes the use of animals in procedures involving no, momentary, or slight pain or distress (e.g., non-invasive parenteral drug delivery, peripheral blood collection, euthanasia, short-term manual or chemical restraint, toe clipping).

Classification D: Includes the use of animals used in procedures that could cause pain or distress but appropriate anesthetics, analgesics, and/or tranquilizing drugs or other methods for relieving pain or distress are used (e.g., surgery, perfusion, administration of irritating chemicals, humane endpoint euthanasia).

Classification E: Includes the use of animals in procedures that have the potential to involve pain or distress that will not be relieved with anesthetics, analgesics, tranquilizer drugs, or other method for relieving pain or distress (e.g., negative conditioning, unrelieved post-surgical pain, death without euthanasia).

VI. ASSURANCE:

The information contained herein is accurate to the best of my knowledge. I have carefully compared the proposed work with the current state of knowledge in this field by reviewing the literature and it is my professional opinion that the proposed work meets high standards of scientific merit. If the study involves pain and distress to the animal, whether or not it is relieved by anesthetics or analgesics, I have (1) reviewed the literature related to this work and have found no significant studies which could make this protocol unnecessarily duplicative, and (2) considered alternatives to animal use and found none available, as described above. Procedures involving animals will be carried out humanely and all procedures will be performed by or under the direction of trained or experienced persons. Any revisions to animal care and use in this project will be promptly forwarded to the Institutional Animal Care and Use Committee for review. Revised protocols will not be used until Committee clearance is received. The use of alternatives to animal models has been considered and found to be unacceptable at this time.

The principal investigator, by signing below, and the IACUC recognize that other medications may be given to the animals for veterinary care purposes. This includes the humane euthanasia of animals in uncontrollable pain or distress as determined by the Attending Veterinarian or the Clinical Veterinarian acting for the Attending Veterinarian. However, the veterinarians will make all efforts to contact and discuss the case with the Principal Investigator or designee prior to making a unilateral decision.

09/27/16

Principal Investigator –Print Date

Principal Investigator Signature Date

NOTE: Principal investigators must submit a current curriculum vitae or biosketch that reflects their most recent pertinent experience**.**

PERSONNEL CHART

ASU requires that all personnel engaged in animal research or teaching be qualified through training or experience in order to conduct the work humanely. The IACUC requires the following training:

- **Level I Basic** – Required of ALL participants (must be renewed every 4 years)
- **Level II Species-Specific** – Required for each participant that will have direct contact with that species (must be renewed every 4 years)
- **Level III Hands-on Training** – Required to perform specific procedures independently; Level III Certification form must be submitted to the IACUC office by the person providing the training within 5 days of the training

You can access the training modules at http://hazel.forest.net/latanet/client/asu/introduction.htm. See the IACUC web site (http://researchintegrity.asu.edu/training/useofanimals) for more information on training and Level III forms.

Name	Title	ASURITE name	Role in Protocol: What procedures will each person be doing on live animals under supervision?)	Role in Protocol: What procedures will each person be doing on live animals independently (without supervision)?	Species with which individual will have direct contact ("none, "all", or list species)	FOR IACUC USE ONLY: Training Confirmation
[redacted]	PI	[redacted]		Responsible for overall conduct of all studies	*Felis catus*	Basics 5/2013 Cat 11/2013 OHSP
[redacted]	Lab Coordinator	[redacted]	assist with surgeries	Conduct daily experiments	*Felis catus*	Basic 5/2013 Cat 11/2013 OHSP
[redacted]	Graduate Assistant	[redacted]	assist with surgeries	Conduct daily experiments	*Felis catus*	Basic 6/2013 Cat 11/2013 OHSP
[redacted]	Undergraduate Assistant			Assistance with training, handling	*Felis catus*	Basic 5/2015 Cat 3/2016 OHSP

For each individual, describe the individual's years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training:

[redacted] has over 10 years experience working with this species and performing surgeries described in this protocol. [redacted] and [redacted] have 3 years experience working with this species. [redacted] has been performing her role with this species for 7 months.

DETAILED USE OF ANIMALS
This section must be completed for each species used.

(additional Detailed Use of Animals forms can be found at https://researchintegrity.asu.edu/animals/forms)

Common Name: Cat

Scientific Name: *Felis catus*

I. ANIMAL INFORMATION

A. Is this a threatened or endangered species?
- ☒ No. Proceed to section I. B.
- ☐ Yes. Describe why this work must be done on this species and why the project will not have a significant negative impact on the species:

B. Maximum # of animals to be used over the 3-year life of the protocol: 5

C. Sex: M or F Age or Weight Range: 1 to 10 years

D. Source (e.g., commercial, in-house breeding, captured from wild): Commercial breeders

E. List all labs and/or rooms **outside of the ASU centralized vivaria** where you intend to keep or use live animals in connection with the animal use covered under this protocol. This list is for IACUC information to assure each location is inspected semi-annually. **Listing rooms here does not assure approval of this space for use.**

Building	Room #	Max Length of Stay	Method of Transport	Purpose

F. If you use DEA-controlled substances, list the location where they are stored (building and room number). If you acquire controlled substances from DACT for same day use, state this. The IACUC is required to inspect all controlled substance storage locations semi-annually.

All DEA substances will be provided by DACT for same day use.

II. MAJOR CATEGORIES OF USE

A. Will animals be immunized for antibody production?
- ☒ No. Proceed to section II. B.
- ☐ Yes. Complete the following table.

Injection:

Volume of injectate	Adjuvant	Route	Min. Frequency	Max. # of injections

Collection: If terminal, check here ☐ otherwise complete the following.

Route	Max. Volume	Min. Frequency	Max. # of collections

B. Will tissues, blood, or other body fluids be harvested (other than for antibody production)?
- ☐ No. Proceed to section II. C.
- ☒ Yes. Will tissues, blood, or other body fluids be collected post-mortem only?
  - ☒ Yes. Proceed to section II.C.
  - ☐ No. Complete Appendix 1: Antemortem Specimen Collection.

C. Will animals be food restricted (calorically or specific constituents)?
- ☐ No. Proceed to section II. D.

☒ Yes. [note: restriction paradigms exceeding a single 24-hr period must follow the ASU IACUC Standard Institutional Guideline for Food and Water Restriction available at http://researchintegrity.asu.edu/animals/SIG

1. What are the restriction parameters? Provide scientific justification and include the length of restriction.
   Animals will be food restricted the night prior to any surgical procedure.

   Animals will also be food restricted for ~3 hours prior to being anesthetized for microstimulation. Microstimulation sessions will be separated by a minimum of 3 days, but will more likely occur once every 1-2 weeks.

2. How will you monitor for negative effects of food restriction (include information on how you will account for animal growth)?
   Since fasting will only occur overnight at maximum, insignificant effects are expected. Fasting overnight prior to surgery is a common practice to empty the stomach and thus minimize the possibility of vomiting and aspiration while anesthetized.

D. Will animals be water restricted?
☒ No. Proceed to section II. E.
☐ Yes. [note: restriction paradigms exceeding a single 24-hr period must follow the ASU IACUC Standard Institutional Guideline for Food and Water Restriction available at http://researchintegrity.asu.edu/animals/SIG

1. What are the restriction parameters? Provide scientific justification and include the length of restriction.

2. How will you monitor for negative effects of water restriction (include information on how you will account for animal growth)?

E. Will animals be exposed to trauma, injury, burning, freezing, electric shock, UV radiation, magnetic fields, lasers, loud noise, or other physical agents that might cause distress?
☒ No. Proceed to section II. F.
☐ Yes. List and justify each exposure.
Provide scientific justification:

F. Will animals be exposed to environmental stress (e.g., non-natural temperature exposure, prolonged physical restraint, forced exercise)?
☐ No. Proceed to section II. G.
☒ Yes. List and scientifically justify each exposure.
The cats may be restrained during neural recordings. This restraint device consists of a zippered bag that encloses the cat's body and limbs but not the cat's head. In order to minimize the stress this may cause, the animal will be pre-conditioned to the bag. It will be used as part of the animal's bedding in their home cage and they will receive positive reinforcement via treats while they are exposed to the bag. Experiments will not begin until the animal is sufficiently acclimated to the restraint bag.

G. Will animals undergo surgery?
☐ No. Proceed to section II. H.
☒ Yes. Complete Appendix 2: Surgical Procedures.

H. Will any animals have a device (e.g., thermocouple, cannula, electrode) that extends chronically through the skin?
☐ No. Proceed to section II. I.
☒ Yes. Describe wound management measures to minimize chances of infection around the device where it penetrates the skin:
The improvements we have made to the implants and surgical procedures have greatly reduced the need for any active long-term care of the implants [redacted] This, including our own observations and the advice of a neurosurgeon at [redacted] indicate that observation is the best course of action. However, the implant connectors are monitored for any issues, and may require cleaning with Betadine or chlorhexidine in the case of an infection.

I. Will animals need any special husbandry considerations, including but not limited to single housing individuals of social species (e.g., rodents) or altering standard cage type, cage change frequencies, or housing temperature?
No. Proceed to section II. J.
Yes. Describe special procedures and provide scientific justification:

J. Will any work be conducted in the field (this includes field experiments or the capture of animals to be used in laboratory experiments)?
No. Proceed to section II. K.
Yes. Complete Appendix 3: Field Research.

K. Will any animals need to be individually identified?
No. Proceed to section III.
Yes. Describe the marking technique to be used, why that technique was chosen, how it will be performed, and on what age range of animals?
They will be identified by their individual natural markings if possible, but if necessary they may have an identifying microchip injected subcutaneously.

III. CHEMICALS AND OTHER POTENTIAL HAZARDS

(If you answer yes to any of the following questions, this information may be forwarded to another oversight unit to aid you in assuring safe practices. Approval by these units or additional training may be required prior to using any of these materials)

A. Will drugs or chemicals be used in animals?
No. Proceed to section III. C.
Yes. For each drug or chemical, list the agent, dose, route, purpose, and grade in the table below:

Agent	Dose	Route	Purpose	Frequency	Pharmaceutical grade (Y/N)?	Is this a DEA controlled substance (Y/N)?
Acepromazine	0.02 - 0.1 mg/kg	IM or SC	Sedative	As needed	Y	N
Amoxicillin	6.6 - 20 mg/kg	PO	Antibiotic	BID for ~10 days post-op	Y	N
Ampicillin	10 - 20 mg/kg	IM or SC	Antibiotic	Once, SID as needed	Y	N
Atropine	0.02 - 0.04 mg/kg	IM or SC	Reduce respiratory secretions and prevent bradycardia	As needed	Y	N
Baytril	5 mg/kg	PO or IM	Antibiotic	SID for ~10 days post-op	Y	N
Betadine	N/A	Topical	Clean implant	As needed	Y	N
Buprenorphine	0.01 - 0.03 mg/kg	IM	Analgesia	q12 hr, as needed	Y	Y
Buprenorphine SR	0.12 mg/kg	SC	Analgesia	Once	Y	Y
Bupivacaine	0.5 - 1 ml	SC	Local anesthetic	Once, as needed	Y	N
Chlorhexidine	N/A	Topical	Clean implant	As needed	Y	N
10% Formalin ± 20% glycerin	4 L	IV	Perfusion	Once	N	N
Glycopyrrolate	0.005 - 0.01 mg/kg	IM or SC	Reduce respiratory secretions and	As needed	Y	N

			prevent bradycardia			
Isoflurane	0.5 - 5%	Inhalation	Anesthetic	Continuous, during surgery	Y	N
Ketamine	2-25 mg/kg	IM	Sedative	As needed	Y	Y
Ketoprofen	1 mg/kg 2 mg/kg	PO SC	Analgesia	SID, up to 5 days Once	Y	N
Lactated Ringer's solution	5 - 10 ml/kg/hr	IV	Fluid support	Continuous, during surgery	Y	N
Meloxicam	0.05 mg/kg 0.3 mg/kg	PO SC	Analgesia	SID, up to 5 days Once	Y	N
Midazolam	0.05 - 0.3 mg/kg	IM or SC	Sedative	As needed	Y	Y
Pentobarbitol-containing euthanasia solution	100 - 200 mg/kg	IV	Euthanasia	Once	Y	Y
Propofol	6 - 8 mg/kg (Bolus) 0.1 - 0.5 mg/kg/min (CRI)	IV	Anesthetic	As needed	Y	N
0.9% Saline solution	5 - 10 ml/kg/hr	IV	Fluid support	Continuous, during surgery	Y	N
Sevoflurane	1 - 8%	Inhalation	Anesthetic	Continuous, during surgery	Y	N
Telazol	10 - 16 mg/kg	IM	Sedative	As needed	Y	Y
Xylocaine	Dab	Topical	Local anesthetic	As needed	Y	N

1. For each drug or chemical that is not pharmaceutical grade, indicate whether no pharmaceutical grade equivalent exists or provide scientific justification for using the non-pharmaceutical grade product.
   10% formalin and 10% formalin with 20% glycerin are not available in a pharmaceutical grade. These will only be used in conjunction with perfusion as a terminal procedure.

B. Does this project involve transgenic animals?
- ☒ No. Proceed to section III. D.
- ☐ Yes. List the strains, any special care needs, and any expected clinical signs that are associated with the strain

C. Does this project involve the use of biohazardous agents in animals (microorganisms, microbial toxins, recombinant DNA)?
- ☒ No. Proceed to section III. E.
- ☐ Yes. List the agent, as well as concentration, dose, and route if applicable.

Agent	Concentration	Dose	Route	ADMIN. USE ONLY	
				ABSL	IBC # if Req'd

D. Does this project involve irradiation or the use of radiological material in animals?
☒ No. Proceed to section III. F.
☐ Yes. List the agent, dose, route, and purpose in the table below:

Agent	Dose	Route	Purpose

1. Provide the **Radiation Safety Committee** approval #:

E. Describe any additional hazardous equipment or materials as well as any non-routine means (e.g., vaccinations, PPE, training, SOPs) used to assure human and animal safety from hazards.
N/A

IV. DETRIMENTAL SEQUELAE

A. Will animals possibly experience clinical signs intentionally or as a possible side effect of the study?
☐ No. Proceed to section V.
☒ Yes. Complete the following.

Possible Clinical Effect	Probability of Occurrence	Treatment
Neurologic symptoms such as: paresis, spasticity, paralysis	1%	Rest, medications/treatments, or removal from study per veterinary recommendation
Infection	5%	Antibiotics (systemic or local), other medications/treatments per veterinary recommendation
Implant Infection	10%	Clean with Betadine or chlorhexidine. Or other treatments per veterinary recommendation.
Post-operative pain	75%	Analgesia regimen. Refer to Appendix 2, section III

V. END POINT CRITERIA

A. What clinical signs will be used as a basis for removal of an animal from the study?
All decisions will be made in consultation with the ASU veterinary staff, but signs include: dangerously decreased or absent eating and drinking, behavior indicating persistent and untreatable pain or severe psychological stress (e.g. self-mutilation, huddled posture, absence of interaction with other animals, extreme resistance to human handlers), and any indication of a serious and untreatable pathology (e.g. blindness or paralysis).

VI. EUTHANASIA

A. List the primary method of euthanasia:
Exanguination and perfusion under anesthesia, in accordance with the IACUC SIG for perfusion. The animal is first sedated as necessary (e.g., ketamine, acepromazine, isoflurane) and then deeply anesthetized with 3-5% isoflurane. Once a deep plane of anesthesia is obtained, the animal is then exsanguinated via cardiocentesis, while 4 L of PBS (a phosphate buffer solution), followed by 4 L of 10% formalin solution, and then by 4 L of 10% formalin solution with 20% glycerin is pumped through the heart in order to fix the brain. In the event a perfusion is not necessary, a pentobarbital-containing euthanasia solution may be used following sedation.

B. If using a chemical or gas, complete the chart below:

Agent	Dose	Route	Is this a DEA controlled	Secondary method used to

			substance (Y/N)?	confirm euthanasia
Pentobarbitol-containing euthanasia solution	100 - 200 mg/kg	IV	Y	Thoracotomy or vital tissue harvest
Ketamine	2 - 25 mg/kg	IM	Y	Used in conjunction with perfusion
Acepromazine	0.02 - 0.1 mg/kg	IM or SC	N	Used in conjunction with perfusion
Atropine	0.02 - 0.04 mg/kg	IM	N	Used in conjunction with perfusion
Isoflurane	3 - 5%	Inhalation	N	Used in conjunction with perfusion
10% Formalin ± 20% glycerin	4 L	IV	N	Used in conjunction with perfusion

For methods that are being conducted in an awake animal (without anesthesia) provide scientific justification:

C. If euthanasia is being done by a physical means (e.g., decapitation, cervical dislocation) without anesthesia, provide scientific justification:

APPENDIX 2: SURGICAL PROCEDURES

I. GENERAL INFORMATION

A. Species
Felis catus

B. Surgical Procedure(s)
Surgical Implantation of Electrode Arrays; Surgical Explantation of Electrode Arrays and Perfusion

C. Room/location of surgery
Vivarium Surgical Suite

II. SURGICAL PROCEDURE:

Survival Nonsurvival

A. Describe each surgical procedure (e.g., approach, tissue manipulation, closure):

Surgical Implantation of Electrode Arrays (Survival)

For this implantation we will follow the procedure outlined in
. In general, surgeries and procedures begin as early as possible to allow sufficient time for completion of the procedure and post-operative monitoring of the patient during hours that the veterinarian is on campus. The animal is premedicated with sedative(s) (e.g., ketamine, midazolam, acepromazine, Telazol) and an anticholeringic (e.g., atropine, glycopyrrolate) or boxed/masked with isoflurane as appropriate based on their medical history or temperament. Ophthalmological ointment will be placed in both eyes to prevent corneal drying. An intravenous catheter is placed in a peripheral blood vessel (e.g., the cephalic vein) to provide intravenous access in case of emergency and to deliver fluid therapy during the surgical procedure. Sterile lactated ringers solution or 0.9% saline solution will be administered IV throughout surgery at an approximate rate of 5-10 ml/kg/hour. The animal will be intubated for continuous administration of isoflurane or sevoflurane. The hair of the scalp is to be removed first with small animal electric clippers, and then more completely with a depilatory if necessary. The skin surrounding the surgical incision site may be infiltrated with approximately 0.5 to 1 ml 0.5% bupivacaine. Injectable antibiotics are also administered on the day of surgery.

Once the surgical preparation is complete, the animal is transported to the operating room and provided with supplemental heat (e.g., circulating heating pad,). Surgical procedures may require that the animal's head be positioned in a stereotaxic frame to ensure that correct location of the brain structure to be studied is obtained. Xylocaine ointment may be applied to the ear bars if needed to provide local pain relief. Vital parameters such as heart rate, ventilatory rate, end-tidal CO_2 ($ETCO_2$), ECG, body temperature, and O_2 saturation will be monitored throughout surgery and recorded approximately every 10 minutes.

Surgical procedures will be performed using aseptic technique. The scalp will be scrubbed with Nolvasan followed by Betadine solution in 3 separate swabbings and the animal's body draped with sterile cloth. The animal may be mechanically ventilated and moderately hyperventilated ($ETCO_2$ about 30 mmHg) to reduce brain swelling while the cortical surface is exposed. A parasagital incision will be made in the scalp exposing the skull overlying the area of cortex where the electrode array will be implanted. Using a surgical drill, up to a 3x3 cm craniotomy will be made in the skull. The dura will be reflected and the electrode array will be lowered onto the cortical surface. In some cases the electrode array may be inserted by hand or using a pneumatic inserter. The dura will be re-approximated and may be sutured closed. Additionally, a layer of dural replacement
or may be placed over the array and dura. The craniotomy may be closed using silicon elastomer. A connector will be attached to the skull using bone screws and the scalp sutured closed around it.

We have previously had IACUC approval for the use of expired [redacted]. [redacted] is only approved for an 18 month shelf life, with the expiration date guaranteeing the sterility/integrity of the packaging, the ability to gel, and the time it takes to gel. The gel is purchased in packs of 5 that cost over $6000. Given the infrequency of our cortical surgeries, we do not use up all the product before expiration. Thus, an already expensive product becomes cost prohibitive to the point of it being essentially unavailable. We tested the efficacy of a vial of [redacted] that expired 08/02/2010 and was over 4 years expired. Since its sterility was questionable, the expired pack was gas sterilized. It was then mixed together per instructions, and it gelled within the guaranteed 3.5 seconds. Based on these results, we would like to be able to use [redacted] that has passed its expiration date by up to 12 months, which is far shorter that the expiration age of the vial we tested. The [redacted] will be re-sterilized before use.

After the procedure, the animal's vitals will be closely monitored and it will be assessed for any abnormal neurologic signs. Systemic analgesics, typically including an opioid (e.g., buprenorphine) and an NSAID (e.g., meloxicam) will be administered and continued post-operatively for several days as needed. Animals may be singly housed post-operatively to allow for quiet recovery and monitoring of appetite and excretion. Antibiotic medication will be administered for at least 5 days post-operatively. Animals will be allowed to recover completely from surgery (5 – 10 days) before undertaking experiments.

Surgical Explantation of Electrode Arrays and Perfusion (Non-Survival if perfused)

The explantation (removal of the electrode array and connector) will be done so we can perform histological and SEM studies of the electrode array, and will be conducted at the completion of the study. This could be up to 6 months post-implantation, but would likely be 1 month or less.

Surgical preparation, anesthesia, and peri-operative monitoring will be as described above. If the animal is to be perfused or euthanized, aseptic technique may not be utilized during the surgery. An incision will be made in the scalp to expose the base of the connector, and the skin surrounding the connector will be surgically loosened and retracted. The bone screws attaching the connector to the skull will be removed using a sterile screwdriver. The connector will then be loosened from the skull. A surgical drill will be used to make a craniotomy surrounding the wires that connect the implant to the connector. Dura and tissue that has covered the surface of the implant will be resected. The implant will be gently removed from the brain by means of forceps, and the entire assembly (connector, wires, and implant) will be placed in saline. The dura will be replaced over the surface of the brain and may be supplemented by artificial dural replacement [redacted] or [redacted]). The craniotomy may be filled with [redacted], at the discretion of the surgeon in consultation with the veterinarian and based on the size of the craniotomy and integrity of the tissue. The animal may then be perfused as described in section VI.

If we do not need to perform histology, we may not perfuse or euthanize the animal and will close the surgical incision and allow it to recover from the explant surgery. In this case, aseptic technique and post-operative analgesia and antibiotic treatment will be performed as described above. When fully recovered from surgery, we will offer the animal for adoption.

B. Anesthetic regimen:

The specific anesthetic regimen may vary based on the individual's needs and temperament; it may include various combinations of the following medications as determined by the DACT veterinary staff.

Drug & concentration (e.g., mg/ml)	Dose (e.g., mg/kg) & maximum volume to be given	Route	Is this a DEA controlled substance (Y/N)?
Acepromazine (10 mg/ml)	0.02 - 0.1 mg/kg (Max 0.1 ml)	IM or SC	N
Ketamine (100 mg/ml)	2-25 mg/kg	IM	Y
Midazolam (5 mg/ml)	0.1 - 0.3 mg/kg	IM or SC	Y
Telazol (50 mg/ml)	10 - 16 mg/kg	IM	Y
Atropine (0.54 mg/ml)	0.02 - 0.04 mg/kg	IM or SC	N
Glycopyrrolate (0.2 mg/ml)	0.005 - 0.01 mg/kg	IM or SC	N
Isoflurane	0.5 - 5%	Inhalation	N
Sevoflurane	1 - 8%	Inhalation	N

Propofol (10 mg/ml)	6 - 8 mg/kg (Bolus) 0.1 - 0.5 mg/kg/min (CRI)	IV	N

1. Describe measures used to indicate a surgical plane of anesthesia to keep animals from getting too light or too deep:

Physiological status and anesthetic depth will be monitored using parameters including reaction to stimuli, ECG, pulse-oximetry, end tidal gasses, heart rate, and ventilatory rate by DACT veterinary personnel. Depth of anesthesia and vital parameter assessment and recording occurs approximately every 10 minutes and is adjusted as necessary based on these observations and measurements.

C. Additional pharmacological agents used during surgery (include analgesics, supportive medications, and research drugs):

Drug and concentration	Dose & max volume	Route	Frequency	Purpose	Is this a DEA controlled substance (Y/N)?
Ampicillin (200 mg/ml)	10 - 20 mg/kg	IM or SC	Once during surgery, SID as needed	Antibiotic	N
Bupivacaine	0.5 - 1 ml	SC	Once, as needed	Local anesthetic	N
Xylocaine	Dab	Topical	As needed when placed in stereotax	Local anesthetic	N
Lactated Ringer's solution	5 - 10 ml/kg/hr	IV	Continuous	Fluid support	N
0.9% Saline solution	5 - 10 ml/kg/hr	IV	Continuous	Fluid support	N

D. Describe the steps taken to maintain an aseptic surgery:

Surgical instruments will be sterilized in an autoclave or with ethylene oxide gas using standard protocols. Surgeons will follow standard scrubbing protocol, and wear a mask, bonnet, and sterile gowning and gloves. The surgical site is cleaned with Nolvasan then prepared with three separate swabbings of Betadine. The swabbings start in the middle of the surgical site and spiral outward. The animal is then covered with sterile cloths. Towel clamps are used to attach the sterile cloths to each other and the underlying cloths, so that only Betadine treated skin is visible.

E. What is the maximum duration of each surgery?
6 hours

F. Will any animals recover from surgery?
☐ No. This involves terminal, or non-survival, procedures; Appendix 2 is complete.
☒ Yes. Complete Section III.

III. POST-SURGICAL CARE

A. Is there a potential for post-operative pain or distress?
☐ No. Proceed to section C.
☒ Yes.

B. Will analgesics be used?
(For analgesic options, refer to the IACUC Standard Institutional Guideline on analgesia (https://researchintegrity.asu.edu/animals/sig) or contact a DACT veterinarian
☐ No. Provide a scientific justification:

☒ Yes. Complete the following.

Drug & concentration	Dose & max. volume	Route	Frequency	Is this a DEA controlled

				substance (Y/N)?
Buprenorphine (0.3 mg/ml)	0.01 - 0.03 mg/kg	IM	q12 hr as needed based on veterinary assessment	Y
Buprenorphine SR (1 mg/ml)	0.12 mg/kg	SC	Once	Y
Ketoprofen (12.5 mg tablet) (100 mg/ml)	1 mg/kg 2 mg/kg	PO SC	SID, up to 5 days Once	N
Meloxicam (1.5 mg/ml) (5 mg/ml)	0.05 mg/kg 0.3 mg/kg	PO SC	SID, up to 5 days Once	N

Who will administer these drugs?
DACT, Lab Staff

C. Post-operative routine care:

i. What drugs will be administered, if any (e.g., antibiotics, fluids)?

Drug & concentration	Dose & max. volume	Route	Frequency	Purpose	Is this a DEA controlled substance (Y/N)?
Amoxicillin (25 mg/ml)	6.6 - 20 mg/kg	PO	BID for ~10 days	Antibiotic	N
Baytril (22.7 mg/ml or 22.7 mg pill)	5 mg/kg	IM (injection) PO (pill)	SID for ~10 days	Antibiotic	N

ii. What other post-operative support and monitoring will be provided, how often, for how long, and by whom?

Post-operatively the animal is continuously monitored until the gag response has returned and the endotracheal tube has been removed. The animal is then transferred to a recovery cage and observed regularly until it is able to maintain a stable sitting posture or is ambulatory. Surveillance for pain begins following recovery from surgery and continues until the animal appears to be pain free without the administration of analgesics. The animal's demeanor, feeding, and interaction with staff are used to identify painful behavior. Opioid analgesics are typically provided for a minimum of 48 hours following implantation of an array. The decision of which analgesic drug to administer is made based on the clinical appearance of the animal, assessment of pain through observation, and knowledge of the degree of difficulty of the procedure performed. Cessation of analgesics will occur once signs of pain are no longer present. Antibiotic treatment usually lasts 5 to 10 days, and may be extended if needed. Provision of all post-operative medications including antibiotics and analgesics is made in consultation with the veterinary staff. Monitoring is provided by both trained DACT and PI personnel.

D. Is post-operative intensive care required?
☒ No. Proceed to section E.
☐ Yes.
What special care is required?

Who will provide special care and what are their qualifications?

For how long will special care be needed?

E. Will animals undergo multiple survival surgical procedures?
☐ No. Appendix 2 is complete.
☒ Yes. Describe which surgeries, the sequence (specifying time between surgeries), and frequency. Provide scientific justification:

This study requires tissue histology once recordings are completed. Typically, the second surgery will be a terminal procedure. However, if we do not need to perform histology, we may not perfuse or euthanize the animal

and will allow it to recover after the explant surgery. In that case, the explant will be necessary, as we will offer the animal for adoption.

From:
Sent: Thursday, November 10, 2016 10:53 AM
To: ;
Subject: Re: 17-1533R Edits

I am good with it too, thanks!

--

Arizona State University

From: >
Date: Thursday, November 10, 2016 at 8:15 AM
To: >
Subject: RE: 17-1533R Edits

I am good with this if is.

From:
Sent: Thursday, November 10, 2016 8:13 AM
To:
Subject: 17-1533R Edits
Importance: High

Hi and ,

At the October IACUC meeting, it was requested that Dr. add references to support the statistical range of animals. Attached is the protocol with those edits. Please let me know if these satisfy the requested edits, and I will go ahead and process it.

Please let me know if you have any questions.

Thank you,

t | f
| http://researchintegrity.asu.edu
How am I doing? Email my supervisor

Customer Service is our priority. Please click here to let me know how I am doing.

STATEMENT OF WORK

Institution – Arizona State University

Title –

Overview

The larger-area high-resolution μECoG grids provided by will be chronically implanted in 5 cats. Neural recordings and in vivo impedance measurements will be obtained each work day for the first 30 days following implantation, and at least weekly for the subsequent two months. The neural recordings and impedance measurements will be performed in the awake animal. Micro-stimulation via the larger-area high-resolution μECoG grids will be perform once per week in each animal. EMG responses to the micro-stimulation will be recorded using sterile fine-wire electrodes placed in the hind limb muscles. Micro-stimulation and EMG recordings will be performed while the feline is anesthetized in order to prevent spontaneous movement and allow placement of the fine-wire EMG electrodes.

Deliverables

1) Provide at least 2 months of neural recording data

2) Provide at least 2 months of micro-stimulation data

3) Provide analysis of neural recording and micro-stimulation quality for all data.

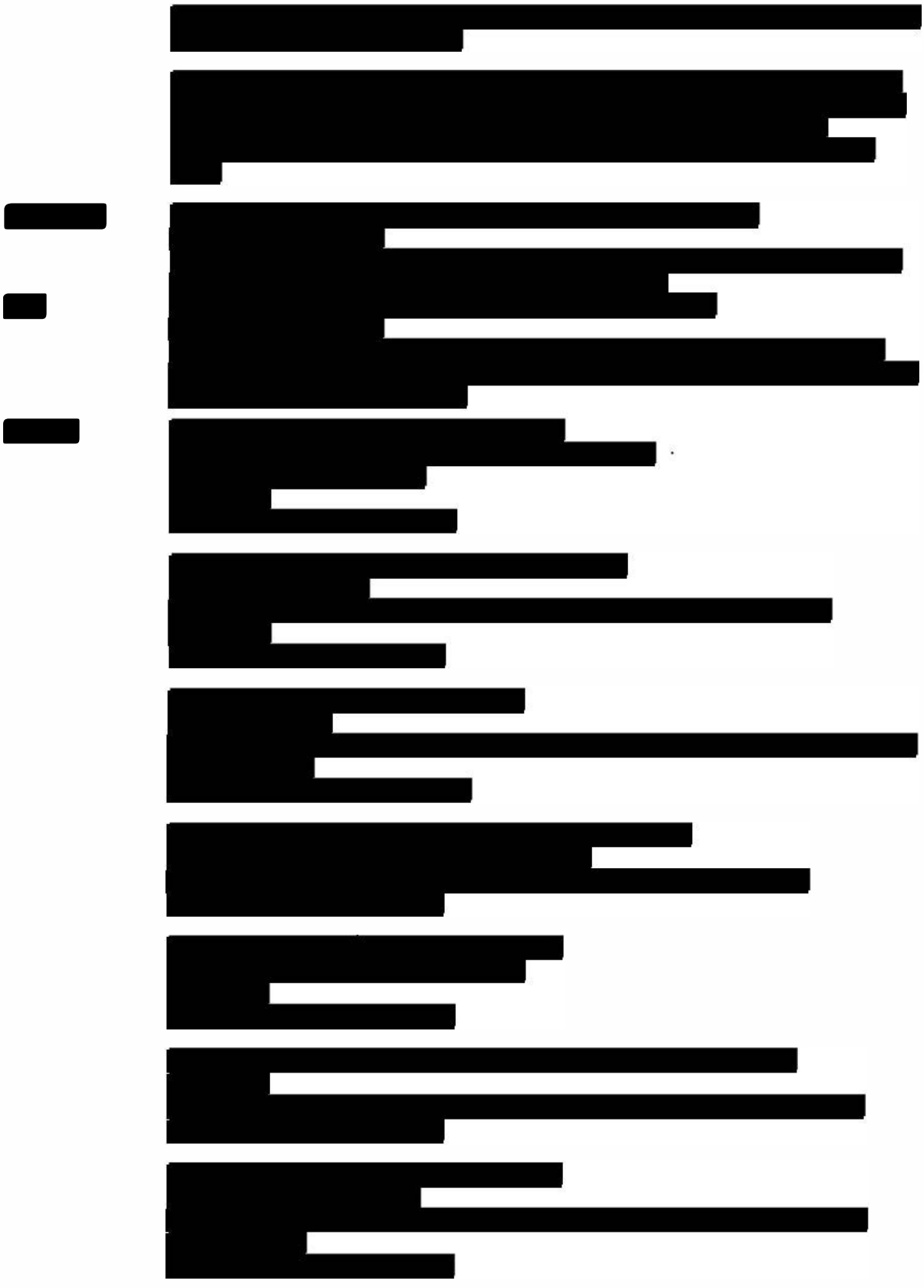
Metrics of Success

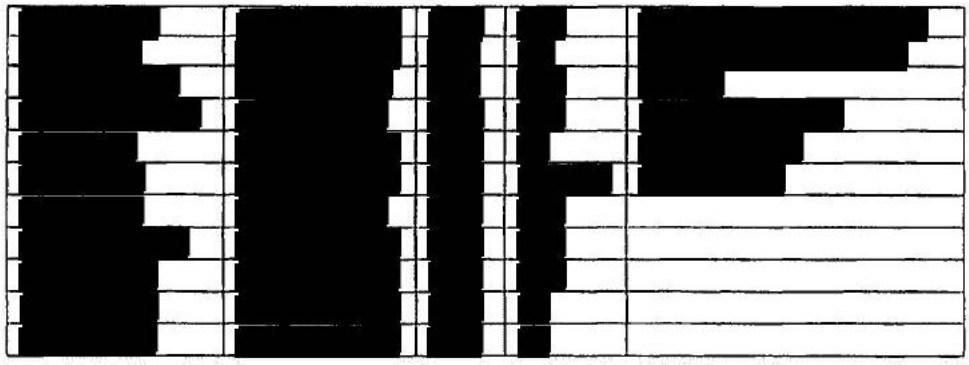
1) The neural data recording metrics, e.g. presence of neural local field potentials, spectrums of local field potential recordings, correlation & coherence of local field potentials across electrodes will serve as functionality metrics for the arrays and neural tissue.

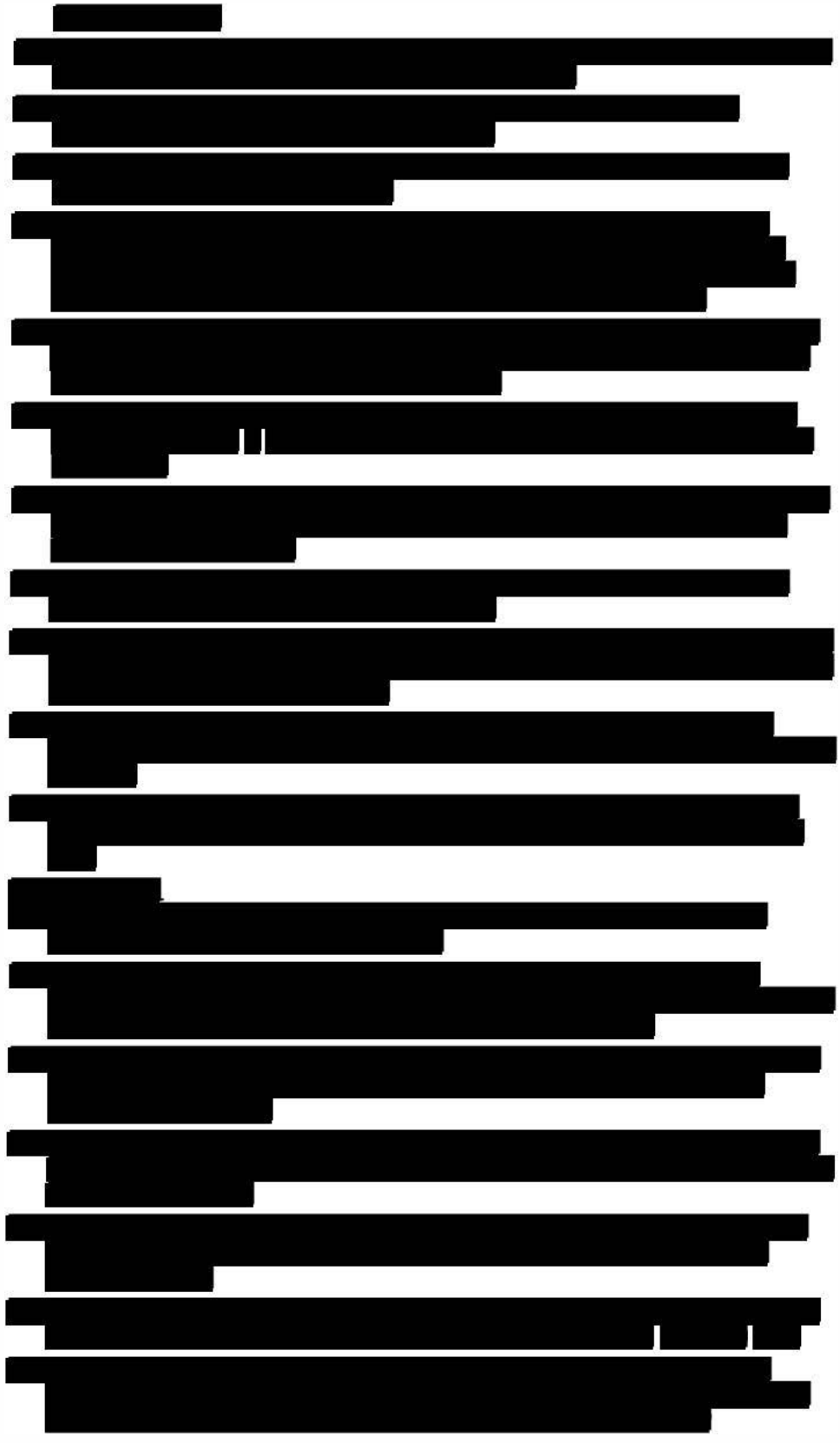
2) Impedance measurements will serve as a metric of electrode viability over the course of in vivo implantation.

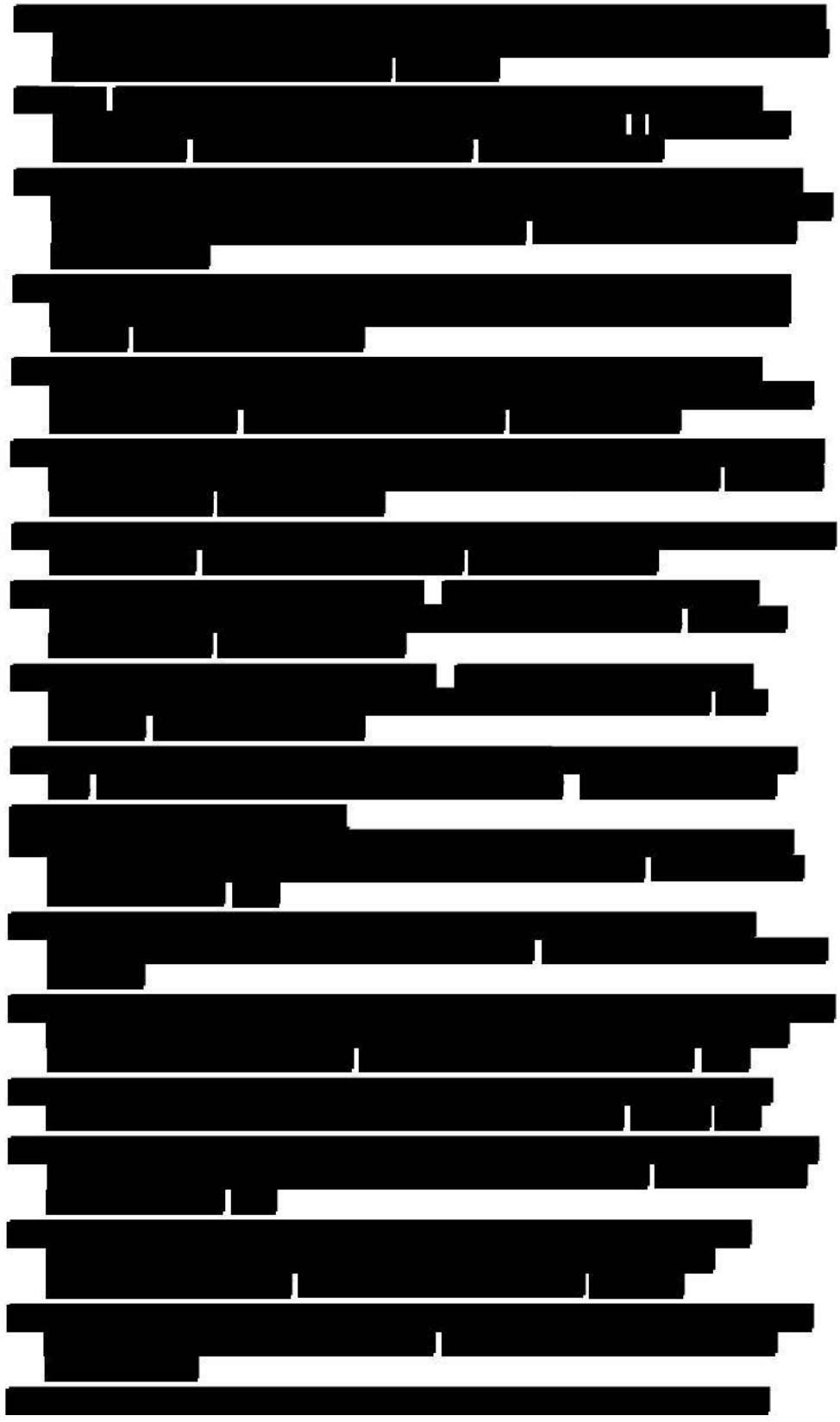
3) Strength-duration curves will be determined for a subset of the electrodes to serve as a comparison with other studies and provide a metric for optimizing stimulation in terms of safety and efficacy.

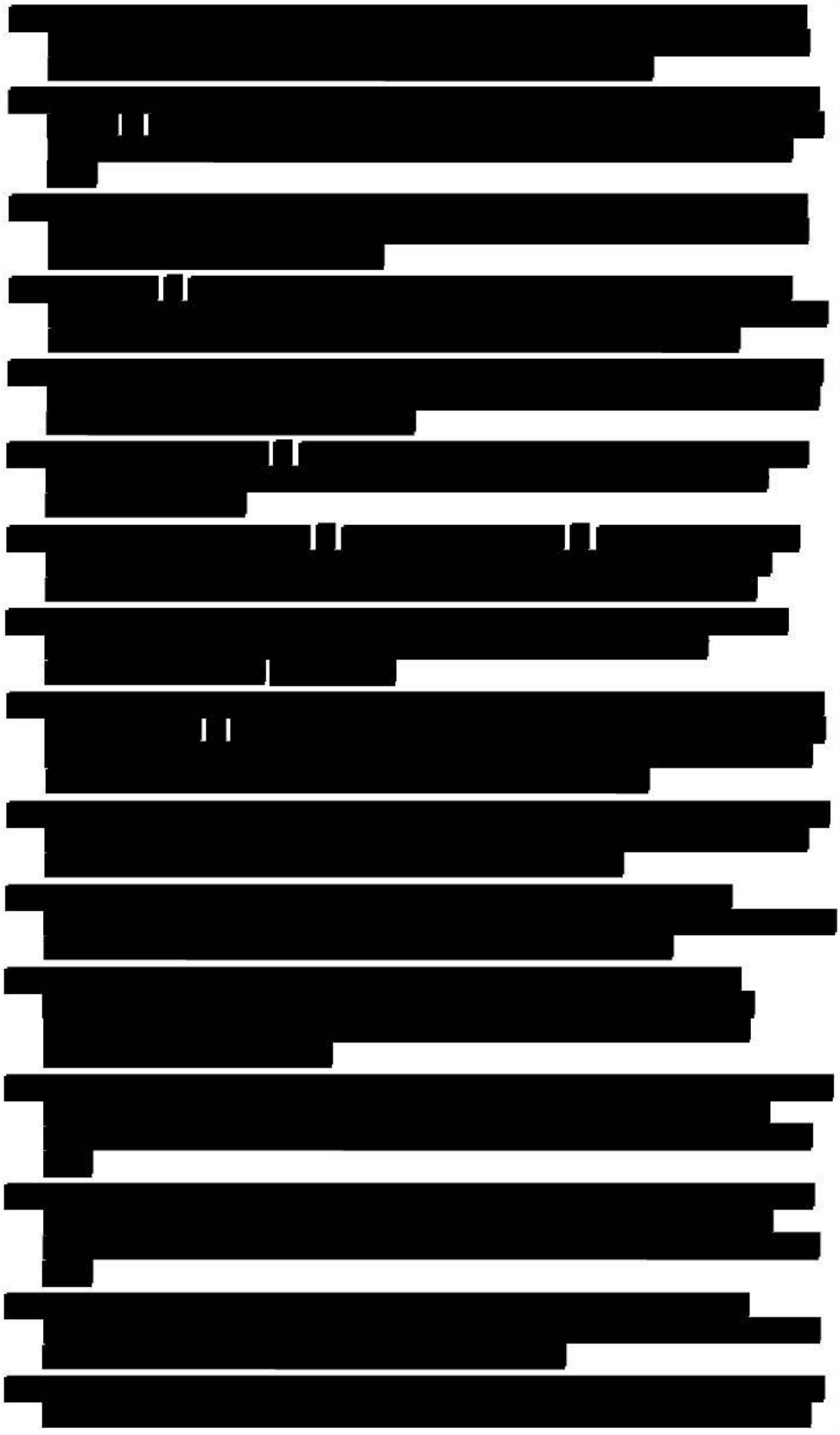
4) Additionally, the ability of micro-stimulation to evoke EMG, and chronaxie and rheobase measurements, will serve as metrics of the physiological efficacy of micro-stimulation.

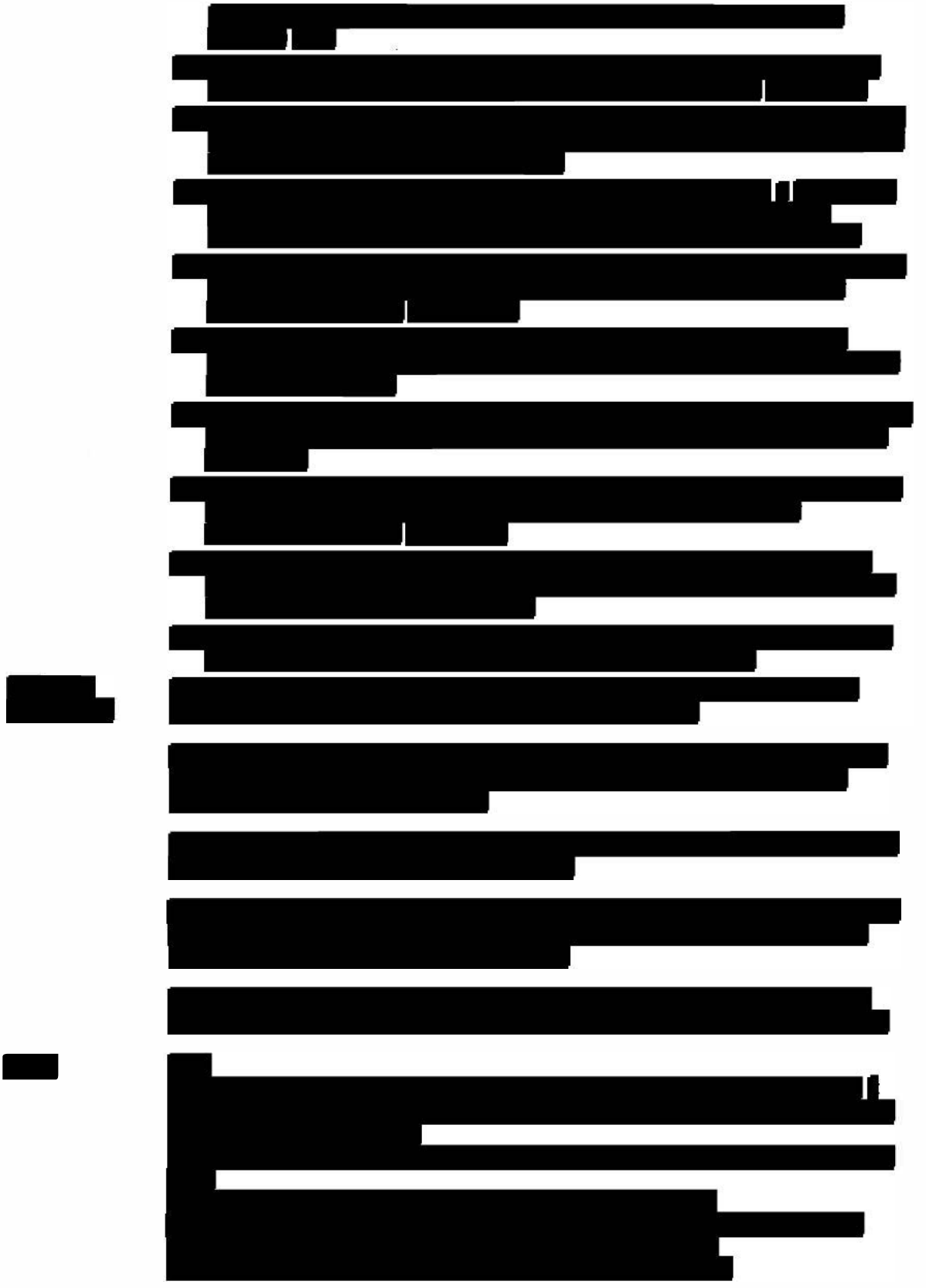












Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity and Assurance
Arizona State University
[redacted]
Phone: [redacted] *FAX:* [redacted]

Animal Protocol Review

ASU Protocol Number: **17-1533R RFC1**
Protocol Title: **Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity**
Principal Investigator: [redacted]
Date of Action: **3/6/2017**

The animal protocol review was considered by the Committee and the following decisions were made:

Request for changes was approved to add [redacted] as additional personnel to the protocol.

If you have not already done so, documentation of Level III Training (i.e., procedure-specific training) will need to be provided to the IACUC office before participants can perform procedures independently. For more information on Level III requirements see https://researchintegrity.asu.edu/training/animals/levelthree.

Total # of Animals: **5**
Species: **Cat** **Pain Level:** **D**

Protocol Approval Period: **11/10/2016 - 11/9/2019**

Sponsor: [redacted]
ASU Proposal/Award #:
Title:

Signature: [redacted] Date: 3/8/2017

Cc: IACUC Office
IACUC Chair

ARIZONA STATE UNIVERSITY

Institutional Animal Care and Use Committee

REQUEST FOR CHANGES TO AN APPROVED PROTOCOL

Protocol No. 17-1533R
Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted] Email Address: [redacted]
If not PI, whom should we contact for questions related to this amendment: [redacted] Email Address: [redacted]

Requested Change (check all that apply):

- ☐ New procedures to be performed – complete Part A and sign assurance.
- ☐ New species and or an increase in the number of animals to be used – complete Part A and sign assurance.
- ☐ New location of housing or procedures – complete Part A and sign assurance.
- ☒ New personnel – complete Part B and sign assurance.
- ☐ Other – complete Part A and sign assurance.

A. Description of Requested Changes
For new procedures or additional animals, list the **Category of Pain.**
If you are adding a procedure that could create pain or distress, you need to include a **literature search** for alternatives.
If you are requesting an increase in animal numbers, provide justification with supportive statistics.
Describe the changes you are requesting.

B. Addition of Personnel

Name	Title	ASURITE name	Role in Protocol (What procedures will each person be doing under supervision?)	What procedures will each person be doing independently (without supervision)?	Species with which individual will have direct contact ("all" or list species)*	IACUC USE ONLY Training (mm/yy)
[redacted]	Undergraduate Assistant	[redacted]	Assistance with training, handling, assistance to graduate students	Assistance with training, handling	all	Basic 2/2017 Cat 3/2017 OHSP

For each individual, describe the individual's training and years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training: [redacted] has no previous history working with this species. He will be trained by [redacted] prior to any handling or training on his own.

Assurance
As Principal Investigator of this protocol, I assure that all procedures will be conducted as described in this amendment and that personnel will receive appropriate additional training prior to conducting any new procedures that are not listed above.

SIGNED:
[redacted]
Principal Investigator

3/6/17
Date

For IACUC use only:

- ☒ Administratively approved - Approving administrator: [redacted] Date of approval: 3/6/2017
- ☐ Administratively handled by VCV - Veterinarian providing verification: Date of verification:
  Sources used for verification:
- ☐ Approved by Designated Review – Designated reviewer: Date of approval:
- ☐ Approved by Full Committee Review – Primary reviewer: Date of approval:

From: [redacted]
To: [redacted]
Subject: FW: Action Required: OHSP Clearance is Expiring 5/20/17
Date: Wednesday, May 03, 2017 11:05:23 AM

Please remove [redacted] from all protocols she is on. ☺

Thank you,

[redacted]
t [redacted] | f [redacted] | http://researchintegrity.asu.edu
How am I doing? Email my supervisor

Customer Service is our priority. Please click here to let me know how I am doing.

From: [redacted]
Sent: Wednesday, May 03, 2017 8:33 AM
To: [redacted]
Subject: FW: Action Required: OHSP Clearance is Expiring 5/20/17

Another removal.

From: [redacted]
Sent: Tuesday, May 02, 2017 6:11 PM
To: [redacted]
Subject: Re: Action Required: OHSP Clearance is Expiring 5/20/17

Hi [redacted],

I am graduating this semester so renewal will not be necessary.

Thank you!

[redacted]

On Tue, Apr 25, 2017 at 3:33 PM, [redacted] wrote:

> [redacted],
> Your Occupational Health and Safety Program clearance is expiring on 5/20/17. You will need to renew your OHSP clearance by that date in order to continue working with animals. To gain Occupational Health clearance, you will need to complete and submit the OHSP Annual Health Surveillance Questionnaire located at https://researchintegrity.asu.edu/animals/forms. The form should be submitted to the IACUC OHSP Nurse at ASU Health Services - [redacted] or

[redacted].
The ASU Fact Sheet for Animal Users and ASU Fact Sheet Animal-Related Asthma and Allergies are also located on the right hand side of the webpage.
For questions, please contact the IACUC Office at [redacted] or [redacted].

Please let me know if you have any questions.

Thank you,

[redacted]
t [redacted] | f [redacted]
[redacted] |
http://researchintegrity.asu.edu<http://researchintegrity.asu.edu/>
How am I doing? Email my supervisor<[redacted]>

Customer Service is our priority. Please click [redacted] to let me know how I am doing.

Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity and Assurance
Arizona State University
[redacted]
Phone: [redacted] *FAX:* [redacted]

Animal Protocol Review

ASU Protocol Number: **17-1533R RFC 2**
Protocol Title: **Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity**
Principal Investigator: [redacted]
Date of Action: **5/8/2017**

The animal protocol review was considered by the Committee and the following decisions were made:

The request for changes was approved to change the stimulation parameters in the protocol.

If you have not already done so, documentation of Level III Training (i.e., procedure-specific training) will need to be provided to the IACUC office before participants can perform procedures independently. For more information on Level III requirements see https://researchintegrity.asu.edu/training/animals/levelthree.

Total # of Animals: **5**
Species: **Cats** **Pain Category: D**

Protocol Approval Period: **11/10/2016 – 11/9/2019**

Sponsor: [redacted]
ASU Proposal/Award #:
Title:

Signature: [redacted] Date: 5/9/2017

Cc: IACUC Office
IACUC Chair

ARIZONA STATE UNIVERSITY

Institutional Animal Care and Use Committee

REQUEST FOR CHANGES TO AN APPROVED PROTOCOL

Protocol No. 17-1533R RFC 2
Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted] Email Address: [redacted]
If not PI, whom should we contact for questions related to this amendment: [redacted]
Email Address: [redacted]

Requested Change (check all that apply):

☐ New procedures to be performed – complete Part A and sign assurance.
☐ New species and or an increase in the number of animals to be used – complete Part A and sign assurance.
☐ New location of housing or procedures – complete Part A and sign assurance.
☐ New personnel – complete Part B and sign assurance.
☒ Other – complete Part A and sign assurance.

A. Description of Requested Changes
For new procedures or additional animals, list the **Category of Pain.**
If you are adding a procedure that could create pain or distress, you need to include a **literature search** for alternatives.
If you are requesting an increase in animal numbers, provide justification with supportive statistics.
Describe the changes you are requesting.

We would like to increase our stimulation parameters for the EMG stimulation described in the parent protocol. Current literature cites stimulation up to 9.8mA using ECoG grids in humans. ([redacted]). Our parent protocol states we will not exceed 1.5mA stimulation in our studies. Therefore, we request to increase the upper limit for stimulate to 4.8mA (maximum our stimulator can achieve).
[redacted])

A primarly reason to increase the current amplitude is that we readily use multiple electrode grids shorted together which thereby increases the demand for a higher current amplitude stimulation. Two electrodes shorted together effectively double the functional surface area when stimulating; four electrodes shorted together quadruple the functional surface area, and so on. Increasing the electrode surface area increases the current amplitude required for stimulation to be effective.

B. Addition of Personnel

Name	Title	ASURITE name	Role in Protocol (What procedures will each person be doing under supervision?)	What procedures will each person be doing independently (without supervision)?	Species with which individual will have direct contact ("all" or list species)*	IACUC USE ONLY Training (mm/yy)

For each individual, describe the individual's training and years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training:

Assurance

As Principal Investigator of this protocol, I assure that all procedures will be conducted as described in this amendment and that personnel will receive appropriate additional training prior to conducting any new procedures that are not listed above.

SIGNED: 5/2/17

_____

Principal Investigator Date

For IACUC use only:

Administratively approved - Approving administrator: Date of approval:

Administratively handled by VCV - Veterinarian providing verification: Date of verification:

Sources used for verification:

Approved by Designated Review – Designated reviewer: Date of approval: 5/8/2017

Approved by Full Committee Review – Primary reviewer: Date of approval:

[redacted]

From: [redacted]
Sent: Thursday, May 04, 2017 8:14 AM
To: [redacted]
Cc:
Subject: Action Required: Designated Review for [redacted] 17-1533R RFC 2
Attachments: [redacted] 17-1533R RFC2 .doc

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

Tracking:

Recipient	Response
[redacted]	
[redacted]	
[redacted]	Yes: 5/4/2017 8:15 AM
[redacted]	Yes: 5/4/2017 8:52 AM
[redacted]	
[redacted]	Yes: 5/4/2017 8:44 AM
[redacted]	Yes: 5/4/2017 12:08 PM
[redacted]	Yes: 5/5/2017 11:02 AM
[redacted]	Yes: 5/4/2017 4:08 PM
[redacted]	
[redacted]	

Designated Reviewer: [redacted]
Principal Investigator: [redacted]
Protocol Number: 17-1533R RFC

A request for an amendment to the referenced protocols has been submitted. The request for amendment is attached and the various related protocols are available at the SharePoint site. The Designated Review process allows IACUC members, by voting, to permit the Designated Reviewer to approve or disapprove an amendment request.

Select "**YES**" if you approve the use of the designated review process for this amendment.

Select "**NO**" if you disapprove the use of designated review process regarding this amendment request. The amendment will then be reviewed at the next monthly IACUC meeting.

Select "**Abstain**" if you would like to abstain from the vote for any reason.

Select "**Recuse**" if you have a conflict of interest.

Please indicate your approval or disapproval of the request for designated review by using the YES or NO button in the toolbar at the top of this message. The use of "YES or NO" buttons allows you to submit comments along with your choice. **You may also send your comments to me directly or to the primary reviewer without using the selection buttons. Please copy me on all correspondence and email related to this request.**

From:
Sent: Friday, May 05, 2017 11:02 AM
To:
Subject: FW: IACUC RFC
Attachments: 17-1533R RFC2 .doc

No problem. Email train is below with the final revised protocol.

Best,

From:
Date: Friday, May 5, 2017 at 10:39 AM
To:
Cc:
Subject: RE: IACUC RFC

Looks good to me.

Thanks!
Best,

Arizona State University

Office:

From:
Sent: Friday, May 5, 2017 9:34 AM
To:
Cc:

Subject: Re: IACUC RFC

Thank you ,

I reworded per your suggestion and accepted all of your changes.

On Fri, May 5, 2017 at 9:12 AM, wrote:

Hi and ,
I just have a couple of edit/wording suggestions for your RFC. Let me know if it looks okay. Otherwise I have no other questions.

Best,
~

Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity and Assurance
Arizona State University
[redacted]
Phone: [redacted] FAX: [redacted]

Animal Protocol Review

ASU Protocol Number: 17-1533R RFC #3
Protocol Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted]
Date of Action: 11/09/2017

The animal protocol review was considered by the Committee and the following decisions were made:

Request for changes was administratively approved to add [redacted] as additional personnel to the protocol.

If you have not already done so, documentation of Level III Training (i.e., procedure-specific training) will need to be provided to the IACUC office before participants can perform procedures independently. For more information on Level III requirements see https://researchintegrity.asu.edu/training/animals/levelthree.

Total # of Animals: 5
Species: Cat **Pain Level:** D
Protocol Approval Period: 11/10/2016-11/09/2019

Sponsor: [redacted]
ASU Proposal/Award #: [redacted]
Title: [redacted]

Signature: [redacted] Date: 11/16/17
IACUC Chair or *Designee*

Cc: IACUC Office
IACUC Chair

ARIZONA STATE UNIVERSITY

Institutional Animal Care and Use Committee

REQUEST FOR CHANGES TO AN APPROVED PROTOCOL

Protocol No. 17-1533R
Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted] Email Address: [redacted]
If not PI, whom should we contact for questions related to this amendment: [redacted] Email Address: [redacted]

Requested Change (check all that apply):

☐ New procedures to be performed – complete Part A and sign assurance.
☐ New species and or an increase in the number of animals to be used – complete Part A and sign assurance.
☐ New location of housing or procedures – complete Part A and sign assurance.
☒ New personnel – complete Part B and sign assurance.
☐ Other – complete Part A and sign assurance.

A. Description of Requested Changes

For new procedures or additional animals that are USDA-covered species, list the **Category of Pain:**
For new procedures or additional animals that are not USDA-covered species, will there be the potential to involve more than slight or momentary pain or distress that will NOT be relieved with anesthetics, analgesics, tranquilizer drugs, or other methods for relieving pain or distress (e.g., negative conditioning, unrelieved post-surgical pain, death without euthanasia)? ☐ No ☐ Yes

If yes, describe and justify:

If you are adding a procedure that could create pain or distress, you need to include a **literature search** for alternatives.
If you are requesting an increase in animal numbers, provide justification with supportive statistics.
Describe the changes you are requesting.

B. Addition of Personnel

Name	Title	ASURITE name	Role in Protocol (What procedures will each person be doing under supervision?)	What procedures will each person be doing independently (without supervision)?	Species with which individual will have direct contact ("all" or list species)*	IACUC USE ONLY Training (mm/yy)
[redacted]	Graduate Assistant	[redacted]		Assist with data collection	all	3/2015 OHSP

For each individual, describe the individual's training and years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training:
[redacted] has no experience working with this species, however they have interacted and handled cats in a home environment. They will be trained by either [redacted] or [redacted] before working on their own.

Assurance

As Principal Investigator of this protocol, I assure that all procedures will be conducted as described in this amendment and that personnel will receive appropriate additional training prior to conducting any new procedures that are not listed above.

SIGNED [redacted]

Principal Investigator — Date 11/9/17

[redacted]

For IACUC use only:

☐ Administratively approved - Approving administrator: [redacted] Date of approval: 11/9/17

☐ Administratively handled by VCV - Veterinarian providing verification: Date of verification:

Sources used for verification:

☐ Approved by Designated Review – Designated reviewer: Date of approval:

☐ Approved by Full Committee Review – Primary reviewer: Date of approval:

Date: 10/09/17

ARIZONA STATE UNIVERSITY
IACUC ANNUAL REVIEW

I. Currently approved protocol

Protocol Number: 17-1533R
Protocol Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted]

II. Status of Project

A. Were the animal activities conducted?

i. ☒ **Yes, they were conducted.** If yes,
   1. Were there any significant animal welfare issues (morbidity or mortality, complications, etc.) encountered over the past 12 months?
      a. ☐ Yes. Please describe (include the problem, approximate number of animals affected, and resolution). Proceed to item II B when completed.

      b. ☒ No. Proceed to item II B.

ii. ☐ **No, they were not conducted.** If the protocol will be terminated, complete the Final Review form.
   1. If the protocol will remain active, why were animal activities not conducted?

      Proceed to Section V.

B. Have there been any recent findings, either from this study or a related study that would change the planned use of animals?

- Species Used
- Animal Numbers
- Procedures
- Criteria to Measure/Monitor Pain or Distress
- Alternatives to Painful Procedures
- Restraint
- Amelioration and Control of Painful Procedures
- Estimation of Potential Postoperative/Intervention Pain
- Postoperative/Chronic Care
- Euthanasia/Disposition of Animals
- Animal Care and/or Use Sites

i. ☐ Yes. Complete a separate Request for Changes form describing all proposed changes as well as the scientific rational for these changes. Proceed to item III.

ii. ☒ No. Proceed to item III.

III. Updated Information

Evaluate the Category of Pain as stated in your currently approved protocol. Do you feel it remains appropriate for the procedures performed?

i. ☒ Yes. Proceed to item IV.
ii. ☐ No. If no, please describe: Proceed to item IV when completed.

IV. Progress Report (for research or teaching protocols only)

Provide a statement on progress under this protocol over the past 12 months. Include any presentations or publications that have resulted from this protocol during the past 12 months.

We have implanted an ECoG grid in 2 animals this past year. In one of the animals, all data has been collected and the grid was explanted. That animal has been adopted out. We have just recently implanted the second animal and data collection will begin within the next couple of day.
We will be presenting a poster of the work in the first animal at the Biomedical Engineering Society Annual Conference in October 2017.

V. Personnel

All personnel who work with animals are required to have animal care training within the last four years. ASU IACUC training modules can be completed a thttps://asu.co1.qualtrics.com/jfe/form/SV_b2b2XRXRRs1309f.

A. List the names, titles, affiliations, and roles of **ALL** persons currently involved in the research or teaching activity.

Name	Title	ASURITE name	Role in Protocol: What procedures will each person be doing on live animals under supervision?)	Role in Protocol: What procedures will each person be doing on live animals independently (without supervision)?	Species with which individual will have direct contact ("none, "all", or list species)	FOR IACUC USE ONLY Training Confirmation
[redacted]	PI	[redacted]		Responsible for overall conduct of all studies	*Felis catus*	Basics 6/2017 Cat 11/2013 OHSP
[redacted]	Lab Manager	[redacted]	assist with surgeries	Conduct daily experiments	*Felis catus*	Basics 4/2017 Cat 11/2013 OHSP
[redacted]	Graduate Assistant	[redacted]	assist with surgeries	Conduct daily experiments	*Felis catus*	Basics 6/2017 Cat 11/2017 OHSP
[redacted]	Undergraduate Assistant		Assistance with training, handling, assistance to graduate students		*Felis catus*	Baiscs 2/2017 Cat 3/2017 OHSP

B. If any of the above listed personnel are new to the protocol, describe their years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training:

C. List the names of any individuals no longer involved with the research (these individuals will be removed from the protocol and DACT will be notified):

VI. Certification

By signing this report, I certify that, to the best of my knowledge, the information included herein is accurate and complete. I understand that continued animal use past the scheduled termination date of the protocol requires IACUC approval. I also understand that should the animal use under this protocol require any change from that stated in the protocol, prior approval by the IACUC is required.

[redacted]

Principal Investigator's Signature

10/9/17

Date

FOR IACUC USE ONLY
Annual Review Determination

ANNUAL REVIEW APPROVAL SIGNATURES:

[redacted]
Chair, IACUC (or Designee)

11/16/17
Date

[redacted]
Attending Veterinarian (or Designee)

11/16/17
Date

[redacted]
IACUC Member

11-16-17
Date

Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity and Assurance
Arizona State University
[redacted]
Phone: [redacted] *FAX:* [redacted]

Animal Protocol Review

ASU Protocol Number: 17-1533R RFC 4
Protocol Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted]
Date of Action: 12/12/2017

The animal protocol review was considered by the Committee and the following decisions were made:

Request for changes was administratively approved to add [redacted] as additional personnel to the protocol.

If you have not already done so, documentation of Level III Training (i.e., procedure-specific training) will need to be provided to the IACUC office before participants can perform procedures independently. For more information on Level III requirements see https://researchintegrity.asu.edu/training/animals/levelthree.

Total # of Animals: 5
Species: Cat **Pain Category:** D

Protocol Approval Period: 11/10/2016 – 1/9/2019

Sponsor: [redacted]
ASU Proposal/Award #: [redacted]
Title: [redacted]

Signature: [redacted] Date: 12/19/2017
IACUC Chair or ***Designee***

Cc: IACUC Office
IACUC Chair

ARIZONA STATE UNIVERSITY

Institutional Animal Care and Use Committee

REQUEST FOR CHANGES TO AN APPROVED PROTOCOL

Protocol No. 17-1533R
Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted] Email Address: [redacted]
If not PI, whom should we contact for questions related to this amendment: [redacted] Email Address: [redacted]

Requested Change (check all that apply):

- ☐ New procedures to be performed – complete Part A and sign assurance.
- ☐ New species and or an increase in the number of animals to be used – complete Part A and sign assurance.
- ☐ New location of housing or procedures – complete Part A and sign assurance.
- ☒ New personnel – complete Part B and sign assurance.
- ☐ Other – complete Part A and sign assurance.

A. Description of Requested Changes

For new procedures or additional animals that are USDA-covered species, list the **Category of Pain:**
For new procedures or additional animals that are not USDA-covered species, will there be the potential to involve more than slight or momentary pain or distress that will NOT be relieved with anesthetics, analgesics, tranquilizer drugs, or other methods for relieving pain or distress (e.g., negative conditioning, unrelieved post-surgical pain, death without euthanasia)? ☐ No ☐ Yes

If yes, describe and justify:

If you are adding a procedure that could create pain or distress, you need to include a **literature search** for alternatives.
If you are requesting an increase in animal numbers, provide justification with supportive statistics.
Describe the changes you are requesting.

B. Addition of Personnel

Name	Title	ASURITE name	Role in Protocol (What procedures will each person be doing under supervision?)	What procedures will each person be doing independently (without supervision)?	Species with which individual will have direct contact ("all" or list species)*	IACUC USE ONLY Training (mm/yy)
[redacted]	Student worker			Assist with data collection, maintain cleanliness of implants	all	Basic 3/16 Cat 11/17 OHSP

For each individual, describe the individual's training and years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training:
[redacted] has no experience working with this species, however they have interacted and handled cats in a home environment. They will be trained by either [redacted] or [redacted] before working on their own.

Assurance

As Principal Investigator of this protocol, I assure that all procedures will be conducted as described in this amendment and that personnel will receive appropriate additional training prior to conducting any new procedures that are not listed above.

SIGNED: [redacted]

11/9/17

Principal Investigator Date

For IACUC use only:

☒ Administratively approved - Approving administrator: [redacted] Date of approval: 12/12/2017

☐ Administratively handled by VCV - Veterinarian providing verification: Date of verification:

Sources used for verification:

☐ Approved by Designated Review – Designated reviewer: Date of approval:

☐ Approved by Full Committee Review – Primary reviewer: Date of approval:

From: [redacted]
To: [redacted]
Subject: Removal
Date: Monday, January 22, 2018 2:33:24 PM

Please remove [redacted] and [redacted] from all protocols that they are on. They are no longer at ASU.

Thank you,

[redacted]
t [redacted] | f [redacted] | http://researchintegrity.asu.edu
How am I doing? Email my supervisor

Customer Service is our priority. Please click here to let me know how I am doing.

From: [redacted]
To: [redacted]
Subject: FW: Removals
Date: Monday, March 26, 2018 12:53:53 PM

Thank you,

[redacted]
t [redacted] | f [redacted] | http://researchintegrity.asu.edu
How am I doing? Email my supervisor

Customer Service is our priority. Please click here to let me know how I am doing.

From: [redacted]
Sent: Monday, March 26, 2018 10:30 AM
To: [redacted]
Subject: Removals

Name	PI
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Thank you,

[redacted]

Institutional Animal Care and Use Committee (IACUC)
Office of Research Integrity and Assurance
Arizona State University
[redacted]
Phone: [redacted] *FAX:* [redacted]

Animal Protocol Review

ASU Protocol Number: 17-1533R RFC #5
Protocol Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted]
Date of Action: 4/20/2018

The animal protocol review was considered by the Committee and the following decisions were made:

Request for changes was approved to add [redacted] as additional personnel to the protocol.

If you have not already done so, documentation of Level III Training (i.e., procedure-specific training) will need to be provided to the IACUC office before participants can perform procedures independently. For more information on Level III requirements see https://researchintegrity.asu.edu/training/animals/levelthree.

Total # of Animals: 5
Species: Cat **Pain Category: D**

Protocol Approval Period: 11/10/2016- 11/9/2019

Sponsor: [redacted]
ASU Proposal/Award #:
Title:

Signature [redacted] Date: 4/24/2018
IACUC Chair or ***Designee***

Cc: IACUC Office
IACUC Chair

ARIZONA STATE UNIVERSITY

Institutional Animal Care and Use Committee

REQUEST FOR CHANGES TO AN APPROVED PROTOCOL

Protocol No. 17-1533R
Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted] Email Address: [redacted]
If not PI, whom should we contact for questions related to this amendment: Email Address:

Requested Change (check all that apply):

☐ New procedures to be performed – complete Part A and sign assurance.
☐ New species and or an increase in the number of animals to be used – complete Part A and sign assurance.
☐ New location of housing or procedures – complete Part A and sign assurance.
☒ New personnel – complete Part B and sign assurance.
☐ Other – complete Part A and sign assurance.

A. Description of Requested Changes

For new procedures or additional animals that are USDA-covered species, list the **Category of Pain:**
For new procedures or additional animals that are not USDA-covered species, will there be the potential to involve more than slight or momentary pain or distress that will NOT be relieved with anesthetics, analgesics, tranquilizer drugs, or other methods for relieving pain or distress (e.g., negative conditioning, unrelieved post-surgical pain, death without euthanasia)? ☐ No ☐ Yes
If yes, describe and justify:
If you are adding a procedure that could create pain or distress, you need to include a **literature search** for alternatives.
If you are requesting an increase in animal numbers, provide justification with supportive statistics.
Describe the changes you are requesting.

B. Addition of Personnel

Name	Title	ASURITE name	Role in Protocol [What procedures will each person be doing under supervision?]	What procedures will each person be doing independently (without supervision)?	Species with which individual will have direct contact ["all" or list species]*	IACUC USE ONLY Training (mm/yy)
[redacted]	Lab Coordinator	[redacted]	Surgical assistance	Assist with data collection, maintain cleanliness of implants	all	8/2014 OHSP

For each individual, describe the individual's training and years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training:
[redacted] has worked with this species in a lab setting for just over 2 years, and has extensive experience handling/interacting in a home environment. She will be trained by either [redacted] prior to working on her own.

Assurance

As Principal Investigator of this protocol, I assure that all procedures will be conducted as described in this amendment and that personnel will receive appropriate additional training prior to conducting any new procedures that are not listed above.

SIGNED: [redacted] 19-Apr-2018
Principal Investigator Date

For IACUC use only:

☒ Administratively approved - Approving administrator: [redacted] Date of approval: 4/20/18

☐ Administratively handled by VCV - Veterinarian providing verification: Date of verification:

Sources used for verification:

☐ Approved by Designated Review – Designated reviewer: Date of approval:

☐ Approved by Full Committee Review – Primary reviewer: Date of approval:

ARIZONA STATE UNIVERSITY

IACUC FINAL REVIEW

I. Terminating protocol

Protocol Number: 17-1533R
Protocol Title: Development of Electrode Arrays to Enhance Efficacy, Biocompatibility and Longevity
Principal Investigator: [redacted]
Termination Date: 10.22.18

II. Check one

☐ The research or teaching was never undertaken.

☒ The research, teaching, or display was conducted.

Describe any significant animal welfare issues, e.g., health problems or accidental deaths, encountered since the last annual review.
None
If you DID NOT purchase your animals through the Department of Animal Care Technology (DACT), did your animal use exceed the predicted numbers approved in this protocol? Yes ☐ No ☒

III. Did the pain status stated on the protocol remain appropriate for the procedures performed? Yes ☒ No ☐

If "No," please provide a brief explanation: ____

IV. Provide a statement on progress of your research under this protocol:
The purpose of this study was to validate a new type of non-penetrating electrode array, while furthering our understanding of the biocompatibility and efficacy of these devices over a long term.

We were able to successfully record signals from the arrays in all animals, but we were not able to elicit any noticeable muscle twitches during microstimulation.

V. Certification

By signing this report, I certify that, to the best of my knowledge, the information included herein is accurate and complete.

[redacted]

Principal Investigator's Signature

12.20.18
Date

FOR IACUC USE ONLY - FINAL REVIEW

Protocol#: 17-1533R **Date Received:** 12/20/2018

COMMENTS:

Confrimed all animals were adopted out end of October/beginning of November.
No animals left in vivarium.

The signatures of the three Designated Reviewers confirm acceptance of the final review.

[redacted]
IACUC Chair or Designee — 12/20/18 Date

[redacted]
Attending Veterinarian or Designee — 12-20-18 Date

[redacted]
IACUC Member — 12-20-18 Date

IACUC Protocol Trackable Components Checklist

Protocol #: 17-1533R If for amendment, amendment #:

PI: [redacted]

Species: Cats Highest Category of Pain: D

Completed by: [redacted] Date completed: 5/3/17

☐ No trackable components in this document

Exceptions to the Guide:

☒ Food/Fluid Regulation
Species: Cat
What Restricted: Food
Parameters: Food is withheld overnight (~16 hours) prior to any surgical procedure, and for ~3 hours prior to microstimulation sessions (minimum duration of 3 days between sessions).

☒ Prolonged Restraint
Species: Cat
Details: Zippered cat restraint bag may be used during recording for up to 60 minutes several times per week.

☐ Husbandry Deviation from the Guide
Species:
Deviation:

☐ Other:

Other Trackable Components:

☒ Survival Surgerie(s)
Species: Cat
Surgerie(s): Surgical Implantation of Electrode Arrays; Surgical Explantation of Electrode Arrays
Multiple Major?: ☒ Yes ☐ No

☒ Hazardous Agents
Biological (list agent and hazard level):
Chemical (note category – toxicant, toxin, irritant, carcinogen, etc.): Toxin – 10% Formalin, 10% Formalin + 20% glycerin
Physical (note type - radiation, UV light, lasers, noise, magnetic fields, etc.):

☐ Non-Centralized Animal Housing
Location:
Maximum duration:

☐ Decapitation

IACUC Protocol Trackable Components Checklist

☐ USDA-covered Species exempt from USDA reporting