

Guideline to Assist in Completing the Institutional Animal Care and Use Committee (IACUC) Protocol for a UC Davis VMTH Clinical Trial

Purpose: The purpose of this document is to help you complete the IACUC protocol for a UC Davis Veterinary Medical Teaching Hospital (VMTH) clinical trial. Please note that the specific details that you need to include in your IACUC protocol for each clinical trial is variable, so not all points made in this document may be applicable to your protocol.

If you have any questions while completing your own IACUC protocol, please contact the IACUC (530) 752-2364 or iacuc-staff@ucdavis.edu) or the Veterinary Center for Clinical Trials (530-752-5366 or vetclintrials@ucdavis.edu).

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General Information about the IACUC Protocol

The Institutional Animal Care and Use Committee (IACUC) is an institution's regulatory office for animal research. This group ensures that all research done using animals (either university- or client-owned animals) is done as mandated by the Health Research Extension Act (HREA) and the Animal Welfare Act. An IACUC protocol must be submitted to describe the procedures to be done to animals in a research study here at UC Davis. Although other individuals can help write or edit a protocol, the Principal Investigator (PI) must have a career staff position.). IACUC protocols must be renewed annually with a de novo review every 3 years.

An IACUC protocol must be approved **BEFORE** starting the study. It can take several weeks (generally 6-8 weeks) to get a protocol approved, so plan ahead!

Getting Started

The first step is to go to the UC Davis [IACUC's homepage](#). There, you will find the link to the online protocol system as well as to many other important and/or helpful resources.

Required Training for Approval on a Protocol

[ACU101](#), an online training course, is required for anyone that is going to work with vertebrate animals on a protocol. It takes approximately an hour to complete.

[Participation in the Occupational Health Surveillance program](#) is required so that the university can monitor your health while you are working with animals and/or hazardous agents. You must have signed up and completed the program before being added to an IACUC protocol. Renewal can vary from 1-5 years depending on individual risks. To get to the application, click on "[Application – Occupational Health and Animals \(OHSS\)](#)". Additional information about the program can be found if you click on the "[Help with the Occupational Health Program](#)" link. Please note that your supervisor or PI is the one to create the Risk Assessment (RA) for you (the participant). You (the participant) will then complete the Health Questionnaire.

Navigating the IACUC homepage

By clicking on the "[Access to the Amendments & Protocol Online System](#)" link, you will be able to access the IACUC online system and get started on an IACUC protocol (you will need a UC Davis Kerberos login and password to enter this system). Although you must submit the protocol online for it to be reviewed, a blank Word document form of the protocol can be found as a reference if you click on "[Protocol Template Form](#) (doc, docx)".

If you are submitting a clinical trial, you are required to submit an **Owner Informed Consent document**. This document can be found if you click on "[VMTH Clinical Trials](#)" and then "Owner Informed Consent form".

[Committee Policies & Guidelines](#) – Although clinical trials do not use research animals, your protocol and research must still follow many of the IACUC policies and guidelines. For example, you may need guidelines/policies on (**not an all-inclusive list**):

- [Blood Volumes, Maximum Blood Draws, and Blood Collection Sites in Small Mammals, Birds and Fish](#)
- [Expired Drugs and Medical Materials](#)
- [Guidelines for Changes in the Use of Therapeutic Drugs on Protocols](#)
- [Non-Pharmaceutical Grade Sodium Pentobarbital](#)
- [Numbers Rationale for Animals in Protocols](#)
- [Training Requirements for Personnel Exposed to Live, Vertebrate Animals](#)
- [Training Responsibilities by Principal Investigators](#)
- [Trials in Non-University Owned Animals](#)
- [Use of Non-Pharmaceutical-Grade Compounds in Animals](#)

Navigating the IACUC/Investigator Menu

On this page, you will find links to:

View amendments and protocols that are pending submission or are submitted,

Initiate and submit new protocols,

Amend active protocols or rosters, and;

View the roster of all active protocols.

IACUC/Investigator Menu

The availability of the options below is based on the active, recently submitted, or partially completed protocols that you are associated with as either P.I., Alternate Contact, or Staff Member.

Name: Christine Kapelewski Active Protocol Number - Title: --Select Active Protocol--

Protocols	Amendments	Animal Tracking & Renewals	Resources
In-Review, Recently Submitted (1) In-Progress, Not Submitted (2) Submit New Protocol	Approved Amendments Denied Amendments (0) In-Review, Recently Submitted (5) Modify Protocol Staff Roster New Amendment Request	Animal Tracking System Renewal Dates	IACUC Home IACUC Policies AAALAC Accreditation Letter PHS/NIH Assurance (A3433-01) USDA Registration (93-R-0433)

Staff Training and Occupational Health Status

-no active protocol selected-

[Status Report - All Active Protocols](#)

Initiating a New IACUC Protocol from an Already Active Protocol

If you are the PI on an active protocol, you can start an IACUC protocol from an already active one. In the IACUC/Investigator Menu, select which active protocol you would like to use as a template from the drop down menu provided.

IACUC/Investigator Menu

The availability of the options below is based on the active, recently submitted, or partially completed protocols that you are associated with as either P.I., Alternate Contact, or Staff Member.

Name: Christine Kapelewski Active Protocol Number - Title: --Select Active Protocol--

Protocols	Amendments	Animal Tracking & Renewals	Resources
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On the IACUC Protocol Form screen, click on the “Start a New Protocol Using This Active Protocol as a Template” link in the top left-hand corner.

IACUC PROTOCOL FORM
View Active Protocol #17583
Originally Approved: 11-Jun-2013 Expires On: 11-Jun-2015

[Start a New Protocol Using This Active Protocol as a Template](#) [Print Front Page](#) | [Print View](#) | [Letter of Verification](#) | [IACUC Menu](#)

This will bring you to an edited version of the already active protocol. Please note that attachments (e.g., informed consent document) **do not** transfer over, so do not forget to add those back in before submitting.

Initiating a New IACUC Protocol (from scratch)

Once you are on the IACUC/Investigator Menu, click on “Submit New Protocol” in the first column of the table under “Protocols”.

Section 1 – Primary Contacts

1. You are automatically entered as the Principal Investigator (PI), so the first real step is to nominate an Alternate Contact. This individual can help with decisions regarding the protocol and will be the individual to step in if the Principal Investigator (PI) is unable to do so (e.g., in the event of an emergency, death of the PI). Including an Alternate Contact is **required** to go on to filling out the rest of the protocol.
 - a. To add an Alternate Contact, enter the last name of the individual you are looking for into the text box provided at the bottom of the screen.
 - b. The system will provide you with a list of individuals with that last name. Select the radio button of the individual you are looking for and then click on “Select”.
 - c. Information for that individual will pop up. Add the after-hours phone number and edit the remaining information if needed. When finished, click “Add Alternate Contact”.
2. To edit the information for the PI or that of the Alternate Contact at any time during the completion of your protocol, click “edit” (located next to “Principal Investigator” or “Alternate Contact”). Don’t forget to add the after-hours phone number for the PI.
3. You can switch the PI and Alternate Contact or even make them the same individual. It is highly recommended to have an Alternate Contact in case of an animal welfare concern and the PI cannot be contacted. So, if you choose to make them the same individual, you will need to designate someone to look after the animals in the event that the PI is unable to do so.
 - **NOTE:** If you are a resident or student filling out a protocol for submission, please note that the PI should be switched to a faculty member prior to submission. If you are writing the protocol on behalf of someone else (like the faculty member) or are completing the protocol for your own project, please make sure to talk with the faculty member that you are putting as PI first. Remember that you are filling out the protocol in their name, so they should be aware of what is written and submitted, as there is no way to edit the protocol once it has been submitted. The only time this information can be edited is after it has gone through the pre-review process.
4. Select the radio button associated with the role for who will be the primary contact for sick animals.

Section 2 – Project Title

1. When you are searching for a protocol to amend (if needed) or to duplicate, you will only be given the title of the project to choose from, so make sure you will know which project is which by creating a detailed title. The title should be consistent between the protocol and informed consent document.
2. Include a clear title for your project. The title should include the “Phase” of the trial (definitions modified from the [National Cancer Institute \[NCI\]](#)):

- Phase 0 = Exploratory trials with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies)
 - Phase 1 = Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans and the side effects associated with increasing dose, may include healthy participants and/or patients
 - Phase 1/2 = Combination of Phase 1 and 2 trials
 - Phase 2 = Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks
 - Phase 2/3 = Combination of Phase 2 and 3 trials
 - Phase 3 = Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained. These trials are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide adequate basis for labeling
 - Phase 4 = Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use
3. **Example:** Phase II trial to examine the effectiveness of Drug A in dogs with XX disease.

Section 3 – Protocol Type

1. For veterinary clinical trials, select “VMTH Clinical Trial”
2. Click “Submit and Initialize IACUC Protocol”

At this point, a screen with very basic instructions will appear. Click “Continue to Protocol Form” to complete the rest of the protocol.

IACUC Protocol Form - Basic Instructions

The Protocol Form is separated into 19 sections. Certain sections will reveal additional requests for information based on information previously submitted. Each section must be completed before the form can successfully be submitted for review. Below are examples of the appearances each section will take depending on its completion status.

<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">1. Incomplete</div> <div style="border: 1px solid #ccc; height: 40px; margin: 5px;"></div> <p>Sections that have not been addressed or are incomplete prior to form submission will appear with no added border.</p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">2. Completed ✓</div> <div style="border: 2px solid #99cc33; padding: 5px; margin: 5px;">a.) completed ✓</div> <p>Completed sections will appear with a yellow border and a green check next to the section title. Completed sub-sections will appear with either a white or blue check next to the sub-section title.</p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">3. Edit Mode</div> <div style="border: 2px dashed #006633; height: 40px; margin: 5px;"></div> <p>When editing a section, a dashed dark green border will appear.</p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">4. Needs Completing</div> <div style="border: 2px dashed #cc0000; height: 40px; margin: 5px;"></div> <p>After submitting the protocol form, any sections found incomplete will appear with a dashed red border.</p>
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Once the Protocol Form has been initiated you may stop at any time and return to complete at a later date or time. Please work on only one section at a time and save your entries before addressing other sections. **Only one section can be updated or entered at a time** and failure to do will result in lost data. Once the form has been completed and successfully submitted, further edits will not be allowed unless requested by the IACUC staff. Lastly, please ensure that Javascript is not disabled on your browser as a good portion of the form's functionality relies on its use. If you have a questions or difficulties while filling out the Protocol Form, please direct them to the IACUC staff (iacuc-staff@ucdavis.edu or 530-752-2364).

Continue to Protocol Form

Completing the IACUC Protocol

General Information

Whenever you want to add something to a section, click on the “Add/Save” button in each section. Otherwise, your work will not be saved!

Section 3 – Protocol Type

Attach the Owner Informed Consent document. Instructions have been included (in red) on the actual Word document. Additional instructions are included at the end of this document.

Section 4 – Species

1. To add or edit Species Information, click on the “add or edit Species Information” link.
2. Enter/Select:
 - a. The common name (e.g., dog)
 - b. Species details (if needed)
 - c. Maximum number required for the trial
 - d. The “source” of the animals (for veterinary clinical trials, enter “client-owned animals”)
3. Click “Add Species to List”

Section 5 – Brief Summary of Procedures

1. Include one or two sentences about the project, including a brief summary of the procedures done to the animals.
2. When finished, click “Add/Save Procedures to Protocol”.

Section 6 – Animal Location(s)

1. *Study Area/Laboratory* –
 - a. If animals will be going to your laboratory or study area **outside the hospital**, include the room number and building.
 - b. If the animals will always be inside the hospital, then select “None/Animals Will Not Leave Animal Facility”.
2. *Overnight Housing (vivaria)* –
 - a. NOTE: This section is linked to the IACUC’s inspection system, so even if the animals are not staying overnight, the IACUC must have a way to determine where animals are being kept and/or used so that they can inspect those areas. Regardless of whether your animals are staying overnight, please complete this subsection.
 - i. Click on “add Vivaria”
 - ii. Select the appropriate option from the drop-down menu.
 - iii. Click “Add Vivarium to List”
3. *Animals will be maintained by* – This question is dependent on the specific experimental procedures involved with the project. Most of the time for clinical trials, you just need to select the radio button for “Vivarium” if hospital staff will take care of the animals as they normally would if they were hospital patients not enrolled in a clinical trial. However, if you (the Investigator) are the one responsible for giving your patient a specific diet (for example) that no one else can give them, you will need to select “Vivarium & Investigator”.
4. Click “Add/Save ‘Maintained By’ Information to Protocol”

Section 7 – Special Husbandry Requirements

1. For the majority of clinical trials, type in “Not Applicable” as the animal will likely be housed as is standard for that species in the VMTH.

2. Per Section 6: If animals will NOT stay overnight (despite what was selected in Section 6), please indicate that animals participating in this study will not stay overnight and that they will go home with their owner after each visit.
3. If there is something not standard about the husbandry, include the information in this section.
4. Click “Add/Save Special Husbandry Requirements to Protocol”.

Section 8 – Hazardous Materials

1. Select Yes or No as applicable.
2. Click “Add/Save Hazardous Materials Information to Protocol”.
 - a. If you clicked “Yes”, a table will appear for you to fill out.
 - b. Click “add Hazardous Materials Information”
 - c. Enter the material type, what the material is and the location where you will be using the material in.
 - d. Click “Add Material to List”
3. Additionally, you will need to provide additional information (addition of Appendix A – Room Lab Safety Sheet) in Section 19.
4. Depending on the actual material, you may also need approval from other committees and offices to use these materials, including the Biosafety Safety Office, Radiation Safety Program, or Stem Cell Research Office (SCRO). Applications you may need to fill out to gain approval could include a [Biohazardous Use Application](#) (BUA), [Radiation Use Authorization](#) (RUA), [Stem Cell Research Office \(SCRO\)](#) application (human stem cell use) and/or laser use application. Information regarding how to handle these materials (either by owners or staff) should be clarified in Section 14. If you have questions about certain drugs (e.g., those used for chemo), please contact the [Environmental Health & Safety](#) (EH&S)’s Chemical Safety Officer at researchsafety@ucdavis.edu.

Section 9 – Special Procedures and/or Activities

1. This section’s selections depend on the project.
2. If the investigational aspect of your protocol revolves around using materials (e.g., anesthesia) or doing procedures normally done in the hospital (e.g., surgery), you still have to check the box for those procedures in this section.
 - a. For example, if you are doing any procedures using anesthesia, select “Anesthetics/Tranquilizers/Sedatives”. You will need to provide details regarding the drugs, dosages, routes, etc. used in Section 14b.
3. Click “Save Changes”.
4. Additional boxes in Section 14 will appear if you select “Anesthetics/Tranquilizers/Sedatives”, “Survival Surgical Procedures”, and/or “Terminal Surgical Procedures”.
5. A text box to provide justification will appear if you select any procedures underneath of the heading “If any of the following procedures or activities are checked...”.

Section 10 – Funding Source(s)

1. Click “add or edit Funding Information”
2. Select the most appropriate options.
3. If you select “Other/None Listed”, provide additional details in the textbox that appears.
4. Click “Add Source to List”.

Section 11 – Veterinary Care

1. Select the most appropriate option for which service will be overseeing the animals.
2. Click “Add/Save Veterinary Services Information to Protocol”.

Section 12 – Objectives and Significance

1. This section should be written in layman’s terms (8th grade level).
 - a. *Objectives* – Outline the goals of your study
 - i. NOTE: This section will be important if you ever need to do an amendment on the original protocol. Amendments must fall within the original protocol objectives otherwise a new protocol would be appropriate.
 - b. *Significance* – Summarize why you are doing this project. Who will it benefit? Why is it necessary?
2. Click “Add/Save Study Objectives & Significance to Protocol”.

Section 13 – The 3 R’s – Refinement, Replacement, and Reduction

1. *Database Search for Alternatives* (Section 13a)
 - a. *Does this project involve USDA covered species?*
 - i. Select “No” if you are involving client-owned animals receiving clinical care or participating in clinical studies.
 - ii. Select “Yes” if you are involving client-owned animals receiving clinical care or participating in clinical studies **with no possible benefit to the animal**. If this is selected, it is recommended that you contact the IACUC staff or the CTRB Chair prior to moving forward.
 - b. If you select “Yes” to the USDA question, the following question will appear: *Does this protocol involve procedures that may cause or have the potential to cause more than momentary pain or distress?*
 - i. Select “No” if your project is non-invasive or is limited to euthanasia or procedures likely only to result in momentary pain (injections, blood collections, imaging), etc.
 - ii. Select “Yes” for procedures that would include surgery, ocular or dermal toxicity testing, inflammatory disease models, use of noxious stimuli, etc.
 1. If you select “Yes”, you will need to do and then document your literature search.

Literature searches for Alternative Procedures:

- a. If you selected “Yes” to both questions for Section 13a, the IACUC/CTRB wants to know whether there are any **alternatives to procedures** that could cause the animal greater than momentary/slight pain or distress.
- b. You need to do a literature search using project-specific terms that are likely to cause pain and distress in the animal. Examples of painful procedures include (but are not limited to) surgeries, biopsies, and tumor growth studies. So, if you are looking to do a biopsy, you will need to do a literature search on whether there are any less painful or distressing procedures that can get you the same or similar results.
- c. **Do not** do a literature search that shows that no one else is doing the science portion or that you need to use animals because in vitro work is not sufficient. Sections 13c and d cover those questions and answers.

- d. Additional assistance can be found at the [UC Davis Center for Animal Alternatives Information](#)
- 2. *Refinement* (Section 13b)
 - a. In this section, you will need to describe what you found during your literature search.
 - b. List any procedures that may cause potential pain and distress and if there are any alternatives to those procedures. If not, state that no alternatives were found and the reason why you can't use any of the ones you did find during that literature search.
 - c. If there are no alternatives to a painful or distressing procedure, describe how you will minimize that pain and distress.
 - i. **Example:** "Through the use of appropriate anesthetics, analgesics and proper handling, we will minimize any potential pain and distress in the animals"
 - d. Click "Add/Save Results of Literature Search to Protocol".
- 3. *Has this study been previously conducted?* (Section 13c)
 - a. For most, the answer is "No".
 - b. Indicate "Yes" if you are replicating a study and provide an explanation as to why you need to redo the study.
 - c. Click "Add/Save Previously Conducted Study Information to Protocol"
- 4. *Replacement (Species Rationale)* (Section 13d)
 - a. Describe why you need to use animals (compared to using in vitro methods or computer simulations).
 - b. Indicate why the specific **species** is necessary to use (i.e., why can't you look at rabbits instead of dogs?)
 - c. Clarify why client animals need to be used and if there is any benefit to these animals.
 - d. Click "Add/Save Species Rationale Information to Protocol".
- 5. *Reduction (Animal Numbers Justification)* (Section 13e)
 - a. If you click "(more)", additional information for what the IACUC is looking for will appear.
 - b. Animal numbers should be a minimum to reach valid results. Justify how you came up with the number of groups and number of animals per group.
 - c. Justification should be based on statistical reasoning (e.g., power analysis) if possible, clinical population numbers, mortality percentages, etc.
 - d. Pilot study numbers should be VERY small (e.g., under 10 animals). You will still need to justify why you need even that number of animals though.
 - e. Click "Add/Save Animal Numbers Justification to Protocol".
 - f. Additional information can be found in the "[Rationale for Numbers and Species in Protocols](#)" guideline.
- 6. *Study Groups and Numbers Table* (Section 13f)
 - a. Click "add or edit Study Group(s)/Numbers
 - b. Group Name/Identifier: Usually a number or "Treatment"
 - c. Species: Automatically inserted based on what you included in Section 4
 - d. Maximum number of animals that you want to enroll per group. You can say "a maximum of XX" or "up to XX", but do not include a range (NOTE: The maximum number of animals for the project comes from what you put in Section 4).

- e. For the Procedures/treatments section, indicate the procedures/treatments that the group will undergo (a list of them is fine).
- f. Click “Add Study Group to List”

Section 14 – Procedure Details

1. *Describe the use of animals in your project (Section 14a)*

- a. Clearly describe all procedures to be done to the animals, including screening processes and inclusion/exclusion criteria. If your project includes hospital procedures that would happen regardless of whether or not the animal was in the clinical trial, make sure to indicate that information **VERY** clearly.
 - i. **Recommended:** Make each procedure (e.g., how to biopsy, contrast enhanced videofluoroscopy, cystocentesis, surgery) its own paragraph. Doing this makes it easier for the reviewer to know what is going on.
- b. Whenever possible, indicate that you will do things aseptically (e.g., catheter placement).
 - i. **Example:** Treatments will be administered intravenously through an aseptically-placed butterfly catheter.
- c. If you are collecting anything (tissue, blood, urine, etc.), indicate the method of collection and the reason for collecting those samples. For blood or tissue collected for stem cells, indicate the volume to be collected. Volume is not required for free catch urine or tissue removed from a tumor.
 - i. **Example:** We will aseptically collect blood via peripheral vein from the dog over 24 hours (at 2, 4, 8, 12 and 24 hour time points) in order to analyze the pharmacokinetics of the drug (levels in the blood) over time. Blood will be collected per the IACUC’s “Blood Volumes, Maximum Blood Draws, and Blood Collection Sites in Small Mammals, Birds and Fish” guideline.
 - ii. **Example:** For blood collection, no more than 1% of the animal’s body weight will be collected within a 14 day period per policy:
<http://safetyservices.ucdavis.edu/ps/a/IACUC/po/bloodVolumes>
 - iii. **Example:** Urine via a free catch or cystocentesis will be collected and analyzed (e.g., urinalysis). If a cystocentesis is needed, it will be done aseptically and in the standard method done at the VMTH (placing a needle into the urinary bladder to collect the urine). Sedation is sometimes needed.
- d. Don’t forget to include a timeline of events (this is helpful for those reading it who are not as familiar with your study and/or do not have a (or your) scientific background).
 - i. **Example:** Week 1 – physical examination, blood collection (CBC, chem panel), urine collection (urinalysis), MRI + anesthesia. Week 2 – injection of drug during craniotomy procedure.
- e. If something experimental is needed from a standard procedure (e.g., a biopsy is collected during a surgery) or you are doing something experimental during the procedure (e.g., injection of stem cells), you must thoroughly describe the standard procedure and the experimental portion.
- f. Avoid getting super specific (e.g., specific needle size, suture type and size) because, if something goes unexpectedly and you don’t end up using that needle size or suture type, it is technically a deviation from the protocol. Use more general terms like “Suitably sized needle”. Instead of giving an exact dose, give a maximum

or a range to give you some wiggle room in case you end up need to give a higher dose than originally expected.

- g. For procedures involving anesthesia being done by the VMTH Anesthesia Service and generally is part of the routine clinical care of the animals and not directly part of the study, please include the following statement: "Anesthesia will be provided and monitored by the VMTH Anesthesia Service and overseen by a veterinary anesthesiologist. The anesthesia service and the anesthesiologist in charge will determine the most appropriate drugs, doses and routes to be used."
 - h. The IACUC needs to ensure that any humans (e.g., faculty, staff, owners) or animals coming into contact with hazardous chemicals or drug, you must indicate how you will minimize exposure. For example, indicate if your VMTH service gives the owner information about the drug being given and/or how to handle it when they are ready to bring their dog home (e.g., do you tell individuals that pregnant women should not handle the chemical or come into contact with the dog's urine following administration?)
 - i. **Example:** We have extensive SOPs written to minimize staff exposure to chemotherapy agents. Owners are instructed how to handle it when they take it home and are given gloves to minimize risk of exposure.
 - i. Clearly state the project endpoint(s).
 - i. **Example:** The study ends after the dog has received the appointment in Week 24. After the study has ended, the dog will go home with the owner.
 - j. Click "Add/Save Summary of Procedures to Protocol"
2. *All drugs and compounds to be administered to the animals* (Section 14b):
- a. This includes experimental compounds, saline, local anesthesia, etc.!
 - b. Click "add Drug Information"
 - c. For anesthetics:
 - i. If done by VMTH Anesthesia Service, include the following:
 - 1. Include common name of species
 - 2. Put "various" for drug and dose
 - 3. For route, leave with the default ("=Select One=") or just choose any route
 - 4. For "When and how often will it be given?", put "The drug routes will be various. Anesthesia to be performed by the VMTH Anesthesia Service"
 - 5. For certain projects the IACUC may ask for additional information relating to the anesthesia, however this will be on a case by case basis so just include the template language on the initial submission.
 - d. For experimental compounds and anesthesia not done by VMTH Anesthesia Service, complete the required fields as thoroughly as possible.
 - e. Click "Add Drug to List"

OPTIONS: If you chose "Anesthetics/Tranquilizers/Sedatives" in Section 9 – Special Procedures and/or Activities, the following sections will appear:

- 3. *Anesthesia Monitoring* (Section 14c)
 - a. If anesthesia will be provided and monitored by the VMTH Anesthesia Service overseen by a veterinary anesthesiologist, indicate this in this section.
 - b. **Example:** Routine monitoring of heart rate, respiratory rate, and blood pressure will be performed by the technician performing anesthesia. These parameters will

be taken into consideration as well as patient movement to determine adequacy of pain control and depth of anesthesia. All specific clinical decisions regarding anesthetic monitoring will be made on an individual case-by-case basis not by the primary investigator. They will be made according to the recommendations of the UC Davis VMTH Anesthesia service.

- c. Click “Add/Save Anesthesia Monitoring to Protocol”

4. *Post-Anesthetic Monitoring* (Section 14d)

- a. **Example:** The following parameters will be used to monitor the patient during the recovery period: temperature, heart rate, respiratory rate and pattern, mucous membrane color and capillary refill time. The anesthesia technician will remain with the patient until swallow reflex is observed and the patient is extubated. Monitoring will continue until the patient is ambulatory. All specific clinical decisions regarding post-anesthetic monitoring will be made on an individual case-by-case basis not by the primary investigator, but rather according to the recommendations of the service clinician assuming primary case responsibility for the patient.
- b. Click “Add/Save Post-Anesthesia Monitoring to Protocol”

OPTIONS: If you chose “Survival Surgical Procedures” in Section 9 – Special Procedures and/or Activities, the following sections will appear in addition to the Anesthesia and Post-Anesthesia Monitoring sections:

5. *Surgery* (Section 14e)

- a. *Surgery Location(s) and Surgeon(s)* (Section 14.e.i)
 - i. Click “add Surgery Information”
 - ii. Select the appropriate Surgery Location and Room number
 - iii. Include the name(s) of each surgeon involved.
 - iv. Click “Add to Surgery Location List”
- b. *Post-Surgical Monitoring* (Section 14.e.ii)
 - i. This section is going to be dependent on the surgery so be as clear and thorough as possible, but should clarify when sutures are removed and that the incision site should be checked daily until the sutures are removed (minimum of 7 days).
- c. Click “Add/Save Post-Surgical Monitoring Information to Protocol”

Section 15 – Adverse Effects

- 1. Clearly describe all significant adverse events from the procedures outlined in your project (even if they are rare), how you will monitor for those events and how you will take care of them if you observe any of the effects. This information should be consistent with what is described in the Consent Form.
- 2. *Criteria for euthanasia* (Section 15d)
 - a. Euthanasia is generally not used in clinical trials; however something needs to be written per federal regulations that bind the IACUC.
 - b. **Example:** We do not expect any animals to die or require euthanasia as part of this study. However, since this is a clinical study with privately owned animals, the decision of euthanasia remains solely at the discretion of the owner.
 - c. Click “Add/Save Adverse Effects Information to Protocol”

Section 16 – Euthanasia

1. Even though euthanasia is not expected, you still need to include information should a catastrophic event occur that requires euthanasia to be performed.
2. Put whatever is done for that species.
 - a. **Example:**
 - i. Species: Dog
 - ii. Method: Overdose
 - iii. Drug: Pentobarbital
 - iv. Dose: $\geq 100\text{mg/kg}$
 - v. Route: Intravenous (IV)
3. Click "Add Method to List"

Section 17 – Disposition

1. Click "Add/Save Disposition of Animals to Protocol"
2. Outline endpoints (i.e., what will happen to the animals at the end of the study).
 - a. **Example:** The patients enrolled in this study are client-owned animals and therefore remain the property of their owners and families. Animals will be discharged to their care after each visit and once the study is completed.
3. Click "Add/Save Disposition of Animals to Protocol"

Section 18 – Roster

1. You will need to add in all major personnel (e.g., faculty, residents, students) that will come in contact with these animals in the roster (exclude technicians, and staff).
2. Click "Add to or edit Project Roster"
3. Enter the Last Name of whomever you are trying to add and select the appropriate option that comes out of the search.
4. Make sure the basic information (email, department, contact information) is up to date.
5. For the Qualifications/Experience section: The IACUC is looking for species-specific and procedure-specific information. They know you are an excellent vet, but anyone else who reads the protocol (e.g., the USDA) may not know that.
 - a. **Example:** "Dr. Doe has 15 number of years experience working with dogs (specify experience related to the species in your protocol) and in performing gastropexy surgeries.
 - b. Please be sure that for anyone conducting surgery, the protocol specific type of surgery and qualifications are stated. So, rather than stating "....experience in all areas of this protocol including surgery..." specifically state experience in performing the type of surgery described in the protocol.
 - c. **Example** of someone who will be trained during the study: Ms. Vet has limited experience (<1 year) and will be properly trained by the PI to handle cats, prepare and maintain implants in a sterile manner, and record activity in cats. This training will be documented.
6. Indicate whether or not you want them to view the protocol.
7. Click "Add Personnel to Roster"
8. The Occupational Health Participation Date and ACU101 Training date will be automatically included IF they have already taken those trainings.

Section 19 – Appendices

This section will only be available if there are any appendices that need to be added, such as if hazards are used in the study .

Assurances for the Humane Care and Use of Vertebrate Animals
Check the “I have read and agree with the above statement” box.

Informed Consent

1. A link to the consent form template can be found [here](#).
2. This document **MUST** be attached to your IACUC protocol when you submit everything. Otherwise, your protocol will be sent back so you can attach it, which will delay approval time.
3. Instructions are included in comment bubbles, so delete them when you are done.
4. Provide answers to each question as thoroughly and clearly as possible. Don't forget that this document will be given to the general public, so please write the answers in layman's terms (8th grade reading level).
5. Within the bold questions, there are a few instances that have “[PLEASE SPECIFY]”, “[DISEASE/CONDITION OF INTEREST]”, etc. appears. Replace those words with the appropriate terminology. For example, replace “[DISEASE/CONDITION OF INTEREST]” with the disease or condition you are assessing in this clinical trial.
6. This document is going to individuals that are going to (hopefully) put their pet in your care, so you want to **PROOFREAD BEFORE SUBMITTING** to the IACUC. Keep the formatting, font type and size consistent throughout the document. Make sure to check spelling and grammar. Depending on your faculty member, you may want to ask your attending faculty member or even someone not in your service to read through the consent form before submitting to make sure everything looks and sounds appropriate. Make sure to complete all of the sections.
7. The protocol number should be added to the header portion of the Consent Form.