Guide for Clinical Research

at the College of Veterinary Medicine

THE OHIO STATE UNIVERSITY

COLLEGE OF VETERINARY MEDICINE

BE THE MODEL

CVM Clinical Research Guide

Table of Contents

CVM Clinical Research Guide

INTRODUCTION

The purpose of this guide is to provide new and established investigators with an overview of the processes, procedures, and resources necessary for conducting clinical research involving privately-owned animals at The Ohio State University College of Veterinary Medicine (CVM).

Any research involving privately-owned animals must adhere to guidelines established by The Ohio State University College of Veterinary Medicine, The Ohio State University Office of Responsible Research Practices, and the USDA.

Principal Investigators working with privately-owned animals in this capacity must follow these CVM Clinical Research Guide to ensure both the integrity of clinical research as well as the regulatory requirements.

Veterinary Clinical Research Support Shared Resource (VCRSSR)

The Veterinary Clinical Research Support Shared Resource (VCRSSR) is supported by the College of Veterinary Medicine, Comprehensive Cancer Center (CCC), and Center for Translational Science Award (CTSA) at The Ohio State University. It comprises both the Blue Buffalo Veterinary Clinical Trials Office (BBVCTO) and Biospecimen Repository (BR). The purpose of the VCRSSR is to support comparative and translational studies in veterinary patients that advance their diagnosis and treatment with the secondary goal of improving human health. As with other shared resources at Ohio State, the VCRSSR is an OSU earnings unit and thus provides services on a fee for service basis.

Clinical Research at the College of Veterinary Medicine (CVM)

The CVM requires Principal Investigators (PIs) to follow the outlined processes for initiating and conducting clinical research in privately-owned animals. Processes vary depending on funding source and it is recommended that PIs review the funding specific flowcharts before proceeding.

Funding sources include:

- **Industry Sponsored**: Small or large companies.
- **Non-Industry Sponsored**: National Institute of Health (NIH), Morris Animal Foundation (MAF), American Kennel Club (AKC), USDA, Winn Feline Foundation, other foundations.
- **Intramural Grants:** C. Glenn Barber funds, CVM grants (Canine, Feline, Equine, Palatin), Mark L. Morris grant, USDA-Animal Health-Formula Funds, Pelotonia, development funds, startup funds.

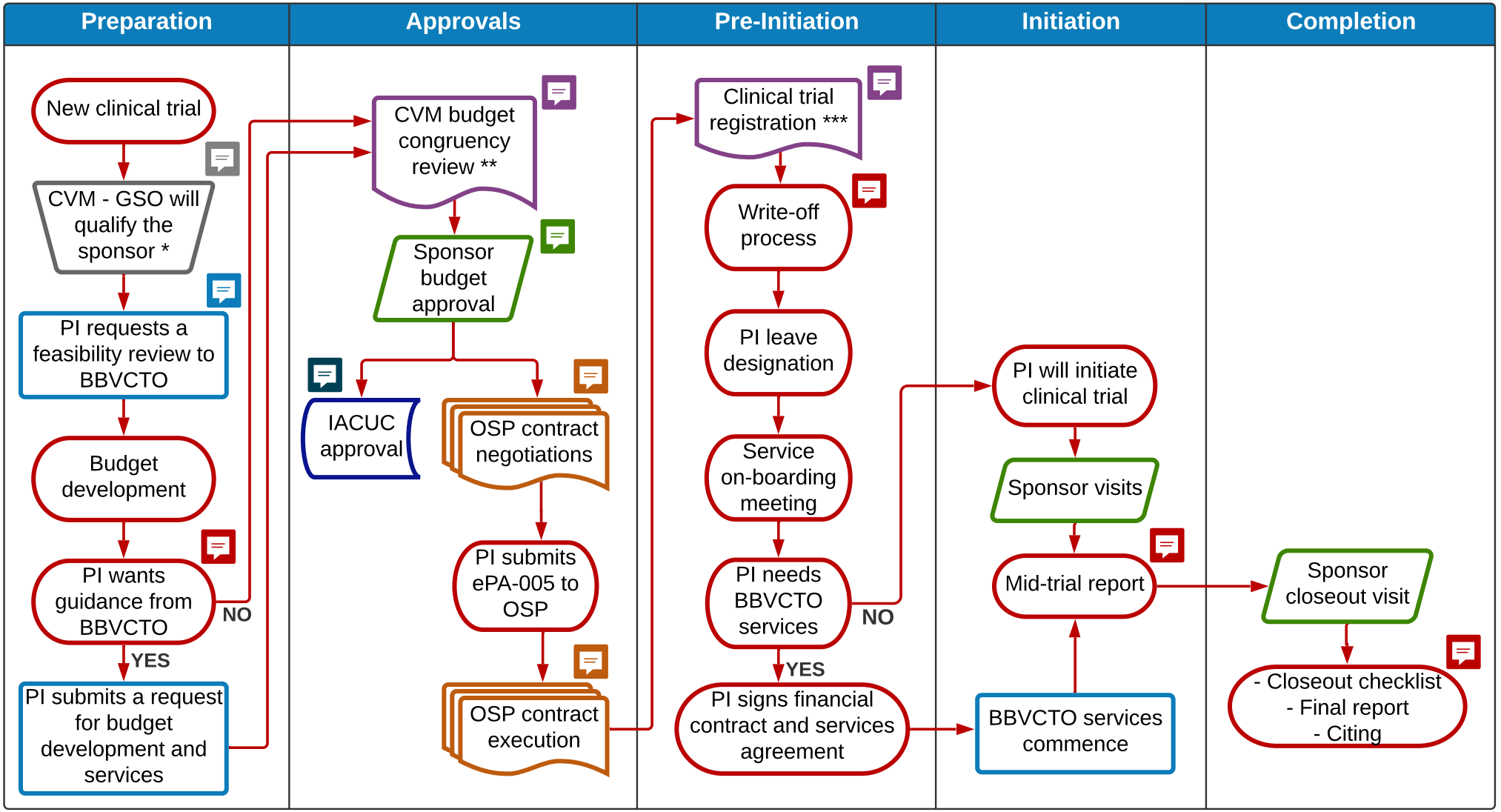
Contact information varies depending on the funding source, for more information visit the CVM Grant Support Office.

Refer to the Industry Sponsored, Non-Industry Sponsored, and Intramural Grants flowcharts as you read through this guide.

Clinical Trial Process Flowchart

Industry Sponsored - 2020

The Ohio State University
College of Veterinary Medicine



* Contact information varies depending on the funding source. More information at the **CVM Grant Support Office**

** PIs conducting any research involving privately-owned animals are required by the College to have the study budget reviewed and approved. This is to ensure that budgets are appropriately formulated in accordance with hospital fees, research discounts, and are congruent with both the study protocol and study calendar. Please be aware that if the budget is formulated and approved well in advance of study initiation, subsequent fiscal increases may represent a problem. Request a budget review **here**.

*** Once a clinical research study has received IACUC approval, the PI should register the study with BBVCTO. This MUST be completed before the study can be initiated. Register a clinical trial **here**.

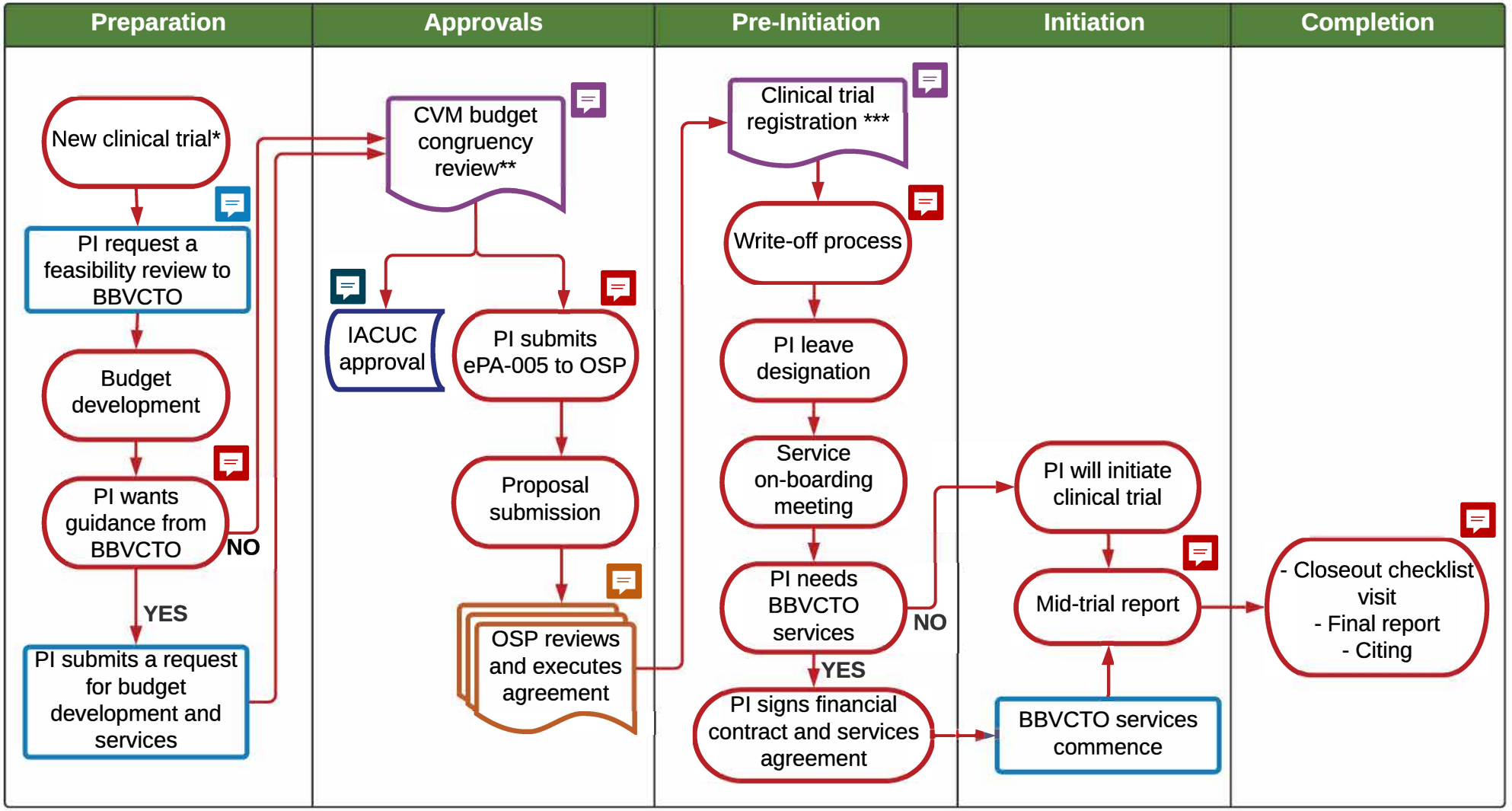
Legend (Links)

- **Principal Investigator (PI)**
- **Grant Support Office (GSO)**
- **Blue Buffalo Veterinary Clinical Trials Office (BBVCTO)**
- **College of Veterinary Medicine (CVM)**
- **Sponsor**
- **Office of Sponsor Programs (OSP)**
- **The Institutional Animal Care and Use Committee (IACUC)**

Clinical Trial Process Flowchart

Non-Industry Sponsored - 2020

The Ohio State University
College of Veterinary Medicine



* Contact information varies depending on the funding source. More information at the **CVM Grant Support Office**

** PIs conducting any research involving privately-owned animals are required by the College to have the study budget reviewed and approved. This is to ensure that budgets are appropriately formulated in accordance with hospital fees, research discounts, and are congruent with both the study protocol and study calendar. Please be aware that if the budget is formulated and approved well in advance of study initiation, subsequent fiscal increases may represent a problem. Request a budget review **here**.

*** Once a clinical research study has received IACUC approval, the PI should register the study with BBVCTO. This MUST be completed before the study can be initiated. Register a clinical trial **here**.

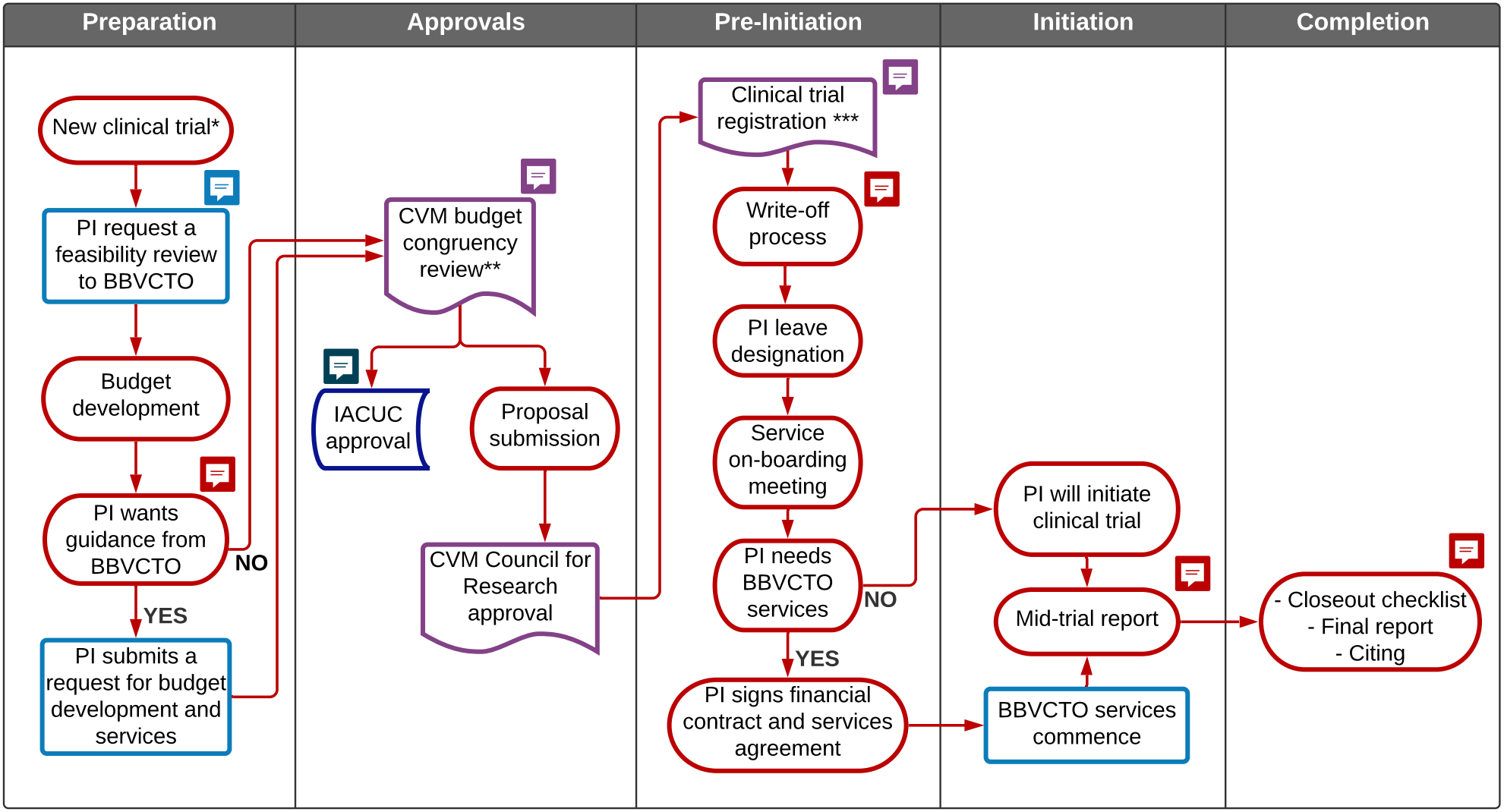
Legend (Links)

— Principal Investigator (PI)
— Blue Buffalo Veterinary Clinical Trials Office (BBVCTO)
— College of Veterinary Medicine (CVM)
— The Institutional Animal Care and Use Committee (IACUC)
— Office of Sponsored Programs (OSP)

Clinical Trial Process Flowchart

Intramural Grants - 2020

The Ohio State University
College of Veterinary Medicine



* Contact information varies depending on the funding source. More information at the **CVM Grant Support Office**

** PIs conducting any research involving privately-owned animals are required by the College to have the study budget reviewed and approved. This is to ensure that budgets are appropriately formulated in accordance with hospital fees, research discounts, and are congruent with both the study protocol and study calendar. Please be aware that if the budget is formulated and approved well in advance of study initiation, subsequent fiscal increases may represent a problem. Request a budget review **here**.

*** Once a clinical research study has received IACUC approval, the PI should register the study with BBVCTO. This MUST be completed before the study can be initiated. Register a clinical trial **here**.

Legend (Links)

— **Principal Investigator (PI)**
— **Blue Buffalo Veterinary Clinical Trials Office (BBVCTO)**
— **College of Veterinary Medicine (CVM)**
— **The Institutional Animal Care and Use Committee (IACUC)**

PREPARATION

1. Documentation requirements

PIs interested in proceeding with a clinical trial need to consider the following:

1.1 Qualification of Sponsor: For industry sponsor clinical trials, the college of Veterinary Medicine (CVM) Grant Support Office, and the Technology Commercialization Office (TCO) will qualify the sponsor and determine the clinical trial needs.

PIs should contact the Grant Support Office for qualifying a sponsor and initial agreement topics. If there are no intellectual property considerations to industry sponsored clinical research, the Grant Support Office will not need to be contacted to qualify the sponsor.

Topics and questions that will inform sponsor qualification follow:

- Confidential Disclosure Agreements (CDA): A CDA is a legally binding agreement that allows parties to have confidential discussions. To request an agreement or to learn more about other uses of a CDA visit the Corporate Engagement Office.
- Material Transfer Agreements (MTA): The college's Office of Research has resources that can help PIs define what types of agreements may be required and help initiate or guide the agreements request processes. The Technology Commercialization Office (TCO) is the point of contact for CDA and material transfer agreement (MTA) request submissions and provides the signatory on behalf of OSU for various agreements.
- Conflict of Interest (COI): All faculty are required to self-report COI information to Office of Research Compliance on an annual basis. A best practice is to ensure your COI submission is current before moving into the steps to develop a clinical trial. The OSU database will be checked as a final step in setting up the agreements for a given clinical trial.
- Funding allocation and timeline expectations.
- Clinical caseload to support the proposed study.
- PI team expertise and commitment to support the proposed clinical research (if the PI was not the original contact).

1.2 Study Feasibility: PIs should submit a Service Request for a feasibility review with the BBVCTO.

2. Budget Development

Key Points

- The scope of work must be defined and finalized prior to developing the budget.
- The source of funding for the clinical research must be defined before budget development.

PIs can submit a Service Request for budget development guidance from BBVCTO.

2.1 Research Rates: Research rates at the VMC apply **ONLY** to not-for-profit foundations, other university studies, OSU intramural funds and development funds. Industry sponsors are for-profit entities and do not receive research rates.

In general, a 20% discount (based on client pricing) will be applied on all VMC charges codes. Discount of pharmacy items are determined by the pharmacy staff and VMC.

2.2 Fiscal Increases: Studies could span multiple fiscal years. OSU and VMC prices could increase each fiscal year (FY start is July 1). PIs should work with the BBVCTO to determine how best to accommodate potential price changes during the course of the study.

2.3 Release-Time (percent effort): PIs should work with John Robinson for calculating release-time, and the cost should be factored as a per year cost for the duration of the study. As with all certification of personnel effort on sponsored projects, the PI's will receive an email alerting them to review and if correct, certify the effort appointed to the project.

Key Points

- If any investigator is receiving release-time/percent effort on a study, this must be evaluated annually to assess whether the release allocation is appropriate.
- It is the PI's responsibility to manage release-time/percent effort and conflict of interest updates.

2.4 Gift Card Incentives: In limited instances, the use of gift cards may be appropriate for patient participation, particularly for survey only research studies. The use of gift cards must be approved as part of the study proposal when reviewed by the Office of Research and Grad Studies. PIs are responsible for following the Policy on Payments to Research Subjects and CVM Guidelines when using gift cards.

Key Points

- Gift cards CAN BE BOUGHT from startups or release-time funds with PRIOR fiscal approval.
- BBVCTO gift card management service only applies to gift cards given to the recipient in person or e-gifts**.**
  - CVM gift card SOP and documents
  - Office of Sponsored Programs

2.5 Multi-Center Trials: Multi-center trials are clinical trials that involve one or more external institutions to which the Ohio State PI is providing oversight.

There are additional budget considerations to be made when anticipating a multi-center trial. A signed Sub-recipient Letter of Intent **Appendix A** will need to be received from all participating sites prior to finalizing the budget.

If third party materials are anticipated for a multi-center trial, MTA aspects will need to be addressed prior to the initiation of the trial. The PI will need to work with OSP on completing and ensuring subcontracts are in place prior to initiation of enrollment at the site.

2.6 Facilities and Administrative (F&A) Costs: also termed overhead or indirect costs.
F&A costs are variable depending on the funding source (industry vs. non-profit) and are used to support institutional infrastructure. **Appendix B**

3. BBVCTO and BR services
BBVCTO and BR can assist in numerous areas including:

3.1 Administrative and Financial Support:

- Protocol design/review
- Budget development/review, VMC Research discounts
- General management
  - Release-time calculation
  - PI Portal account management
  - Grant account management
  - CCTS voucher processing
  - Study contract review
  - Patients write-offs
  - Invoicing

- PMTs - payments
- Subcontracts

3.2 Technical Support: Technical support from BBVCTO will consist of one or more individuals assigned to the trial. The assigned study coordinator will be the liaison for trial-related communications with the PI.

- Study preparation
- Patient procedures
- Sample processing
- Multi-center management

3.3 Research Electronic Data Capture (REDCap) Support: The purpose of REDCap is to provide medical researchers with a professionally managed, secure, web-based, HIPAA compliant environment for building and managing web-based projects.

BBVCTO can create and manage multiple case report forms (CRFs) including:

- Pre-screening surveys
- Patient demographics
- Electronic consent form
- Enrollment form
- Patient history record
- Concomitant medications
- Adverse events
- Note to file, and deviations

3.4 Biospecimen Repository: The Veterinary BR represents a remarkable resource for investigators to develop new prevention and treatment strategies for both animals and people with a variety of illnesses. The Veterinary Biospecimen Repository can collect and store samples of tumors and normal tissue under controlled conditions for future use.
PIs can request BR services through eRamp

3.5 Marketing Support: BBVCTO offers a variety of marketing resources to promote clinical trials and ensure timely enrollment of patients. Many of these marketing activities target regional veterinarians, pet owners and Ohio State University students and staff.
Marketing services can include:

- CVM website and American Veterinary Medical Association (AVMA) website postings
- Monthly content on various newsletters (OVMA, CCC, CCTS, CVM, etc.)
- Email blasts
- Social Media
- Local continuing education events

PIs can request BBVCTO services through an online service request.

Key Point

- It is strongly suggested an initial meeting be scheduled with the BBVCTO when considering conducting a clinical trial at the CVM, or when BBVCTO services are requested. Keeping BBVCTO involved in industry sponsor discussions will ensure immediate support for studies.

APPROVALS

1. CVM Budget Congruency Review

PIs conducting any research involving privately-owned animals are required by the CVM to have the associated study budget reviewed and approved by the BBVCTO. The budget congruency review must

happen BEFORE a PI self-funded study or a proposal is submitted to the sponsor or funding agency, and BEFORE a contract is signed with an industry sponsor.

This is to ensure that budgets are formulated in accordance with hospital fees, research discounts, and other college requirements and are congruent with both the study protocol and study calendar. It is strongly recommended that PIs reach out to the BBVCTO staff early in the process of study design to avoid delays during the congruency review. Budgets funded by internal sources should be submitted prior to initiating the IACUC review process.
PIs can request a Budget Congruency Review submitting the following information:

- Grant
- Calendar of events
- Protocol and consent form
- Preliminary budget
- Other details (Number of centers, salaries)

PIs can download templates of protocols, calendar of events, informed consent form, budgets, and sample collection SOPs at the BBVCTO website.

BBVCTO staff will review the budget to ensure it is congruent with what is proposed in the grant, consent form and calendar of events/study protocol. Comments may be provided. Additional information may be requested if clarification is needed.

Following budget approval, PIs can submit the CVM approved budget to the sponsor for approval.

Key Points

- Any NEW clinical trial requires a budget congruency review. PIs must submit this request at least 10 business days prior to the grant submission deadline.
- Failure of the PI to initiate a budget review via the mechanism detailed above will result in delayed grant submission or commencement of a self-funded study.
- Any ongoing study that needs protocol changes or if the budget has been altered (AMENDMENT), requires a new budget congruency review and a new approval by the sponsor. The agreement for the clinical trial will also need to be amended with the new budget.

2. Institutional animal care and use committee (IACUC)
The IACUC oversees the responsible use of animals in University research and instructional activities. It reviews protocols, the animal care and use program, and monitors university animal facilities to ensure compliance with standards and regulatory requirements.

Any study using privately-owned animals is considered clinical research. All clinical research conducted at The Ohio State University CVM currently requires approval from the IACUC Subcommittee through the submission of an Animal Use Protocol.

2.1 Submitting your Animal Use Protocol to IACUC: PIs can visit the Office of Responsible Research Practice to access e-protocol, the online submission portal and investigator guidance.

2.2 Study Team Requirements: For any individual to be listed on an Animal Use Protocol they must be provided an account in e-Protocol by completing the e-Protocol registration. Individuals who have not registered will not have access to e-Protocol and will not be available for selection as a study team member in the system.

2.2.1 Training Requirements: Prior to conducting any research, all study team members that handle and/or perform procedures on clinical trial patients must be added to the respective IACUC, and all members are required to complete specific training and courses including:

1. Animal Usage Orientation and Occupational Health and Safety Training
    - Working with IACUC
2. Occupational Health Program
3. Responsible Conduct of Research (RCR)
4. Conflict of Interest (COI) Screening/Disclosure
5. Experience and Training Narrative

Visit the Office of Responsible Research Practice for information about training requirements for investigators and study team members who are listed on an animal use protocol.

2.2.2 Good Clinical Practice (GCP): GCP training includes a set of guidelines that must be followed when conducting clinical trials to ensure that the rights and well-being of the trial participants are protected and that the data generated in the trial is valid.

2.3 VMC-IACUC Privately-Owned Animals Subcommittee: IACUC protocols and amendments that include activities using privately-owned animals are routed to the Privately-Owned Animals Subcommittee for review and approval. This mechanism will be triggered when a PI from the CVM enters "privately-owned" as an animal source in their protocol.
PIs are required to upload a copy of the informed consent form under the timeline section and a copy of the study plan (grant or other complete study design documents) in e-Protocol as part of the IACUC submission. Failure to include both of these documents will result in a delay of the review process.

2.3.1 Healthy Pets in Clinical Trials: Research involving healthy animals at the VMC requires special consideration and may necessitate additional approval processes. Please see **Appendix C** for specific details regarding studies involving healthy privately-owned animals.

2.4 Informed Consent Form Template: The Veterinary Medical Center, the CVM Office of Research and the IACUC require an approved template that covers pertinent aspects of informed consent for studies using privately-owned animals.

2.5 Amending your approved Animal Use Protocol: Changes in patient numbers and/or study design requires the generation of an amendment and must be approved by IACUC before implementation. Examples of amendments include revisions to consent documents, changes in PI, addition or change in study team, increase in patient numbers, change in medications or dosages, and inclusion of additional risks or procedures.

Key Point

- Failure to submit an IACUC amendment for a study in which elements have been changed or patient numbers have increased may result in termination of the study.

3. Contract Negotiations

The Office of Sponsored Programs (OSP) will work with the sponsor to put into place a Clinical Trial Agreement (CTA) with the appropriate terms and conditions for the clinical trial/research.

Key Point

- While contract negotiations are typically associated with industry-sponsored contracts, agreements received from non-industry sponsors often require negotiations prior to acceptance by the University.

Materials may be supplied from the sponsor or a third party for the clinical trial. Most material requirements can be handled within the clinical trial agreement; however, some trials may require a separate material transfer agreement (MTA).
MTAs govern the terms under which materials can move into and out of the Ohio State Corporate of Engagement Office. They cover the permitted uses, length of time the materials can be used, and the specifics on the transferred materials.

3.1 EPA-005: The EPA-005 is the university's proposal pre-approval application used by investigators submitting proposals to external sponsors. A fully signed ePA-005 must be available to the Office of Sponsored Programs prior to proposal submission or contract execution.

Key Point

- An EPA-005 is required only for extramural submissions.

3.2 Contract Execution: Study account numbers are provided by OSP to the PI shortly after the full execution of the contract or notice of award. PIs who are recipients of intramural awards will be notified by Michele Morscher in the CVM Office of Research. MTA terms can also be included in the clinical trial agreement. In many cases, the sponsor may also seek to use their template. If so, just attach that to the MTA request you submit Post-Contract Execution.

PRE-INITIATION

1. CVM IACUC Study Registration and Reporting

Registration is required for both new and amended studies. This is a requirement per the college Office of Research and The Ohio State Institutional Animal Care and Use Committee (IACUC) to capture metrics and patient accrual numbers required for yearly reporting to the CVM, CCC, and CCTS.
Upon IACUC approval, the PI will receive an email/approval letter providing a link to complete the required College of Veterinary Medicine Study Registration.

Key Points

- PIs MUST register their clinical trial before the study can be initiated.
- The PI will receive an email notification indicating the Study Registration is complete.

2. Patient Charges Write-Off Process

For trials not managed by BBVCTO, the PI must submit to the VMC Accounting Department a copy of the reviewed budget and study account numbers to provide prepopulated write-off forms that are required for use during the study. The accounting Write-Off SOP can be found at the CVM-Community.

3. PI Leave Designation Protocol

It is recognized that there may be times when the PI is not available due to travel/other commitments/illness. The PI is responsible for putting a plan in place to manage enrollment and continued treatment of study patients during planned and unplanned absences.
Details can be found in **Appendix D**

Key Point

- Failure to follow the PI leave SOP may result in mandatory relinquishment of PI status for the current and additional trials.

4. Service On-boarding Meeting
PI's should inform their service and department chair of their study by providing an on-boarding meeting. Information to be provided:

- Study overview
- Inclusion/exclusion
- Staff involved/contact information
- Study calendar
- Where to find the study protocol and consent forms
- Designated PI when PI is not available

5. BBVCTO Financial Contract
If the PI requested services from the BBVCTO such as technical support, REDCap, marketing, etc. a financial contract via a REDCap link must be completed and signed. This contract will authorize the BBVCTO to review accounts, submit write-offs, and e-requests according to the approved research budget. The contract also authorizes the BBVCTO to generate and submit invoices according to the research contract.

5.1 PI Service Agreement: A service agreement will be generated and signed in REDCap for studies managed by the BBVCTO. The agreement will outline the specific roles and responsibilities of the BBVCTO and PI. A meeting will be scheduled prior to study initiation to ensure that all elements are in place and essential personnel have been on-boarded.

INITIATION

1. Industry Sponsor Visits
Site monitor sponsor visits are typically scheduled throughout the duration of the clinical trial. During the initiation visit the sponsor usually provides the study materials and training. Periodic monitoring visits can occur throughout the course of the clinical trial, and a closeout visit when the clinical trial has been completed at a site.
If the PI requested support from BBVCTO, the individual(s) assigned to the clinical trial will prepare for all sponsor visits.

2. Reporting
The terms in the agreements and protocol which govern a given clinical trial provide details on PI and OSU reporting requirements. These requirements span interim (if applicable) and final reports, publication requirements (Sponsor pre-approval timelines), and potential invention(s) reporting from OSU TCO to the Sponsor. It is the responsibility of the PI(s) to read and understand their obligations.

2.1 Adverse Events (AE) and Serious Adverse Events (SAE): An AE is an unexpected medical problem (e.g. abnormal physical exam or laboratory finding), that happens during the time a patient is on a clinical trial. Adverse events may be mild, moderate, or severe, and may be caused by something other than the drug, or therapy being given.

AEs occurring on IACUC approved protocols are to be reported to the IACUC in a timely fashion via email

A SAE is considered as any of the following: adverse event grade 3 or above, untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, or in the opinion of the investigators represents other significant hazards or potentially serious harm to a study subject. A SAE is considered unexpected if it is not described in the clinical study protocol, or in the informed consent document.

- Veterinary cooperative oncology group – common terminology criteria for adverse events (VCOG-CTCAE) following chemotherapy or biological antineoplastic therapy in dogs and cats.

2.2 Metrics: A REDCap survey will be sent to PIs every 6 months to capture specific study relatedinformation (i.e. enrollment status, number of patients).
PIs also need to report patient numbers to IACUC. See IACUC Policy on tracking animal numbers using eProtocol and guidance document.

COMPLETION

1. Close-out Visit

When an industry-sponsored clinical trial has been completed, a close-out visit will occur. Action items during the close-out visit may include:

- Outstanding case CRFs and queries
- Return or destruction of study drug
- Review of monitoring logs
- Final review of the documents
- Discuss record retention

Timeframes have been established for the length of time BBVCTO will retain study related documents and materials according to study type. See **Appendix E**

1.2 Study Closeout Checklist: See below a list of tasks to be considered upon completion of the study.

Checklist

- ❑ Inform study sponsor when last patient is enrolled.
- ❑ Inform BBVCTO of study closure to ensure web postings are updated.
- ❑ Complete OSP Project Closeout
- ❑ Complete a 6-month REDCap survey confirming study closure date and total enrolled numbers.
- ❑ Contact a CVM Fiscal Officer to stop release-time.
- ❑ Report patient numbers to IACUC.
- ❑ Confirm all data is recorded, signed, dated, and quality controlled (QC) in REDCap, CRFs, other databases, and the CVM electronic medical record (EMR).
- ❑ Determine whether remaining samples, medication, or study supplies need to be shipped.
- ❑ Provide the Biospecimen Repository with a plan for any current or long-term stored study samples.
- ❑ There may be other requirements per the CTA.

2. Reporting

Once a study is closed, PIs will receive an annual REDCap survey to capture information regarding publications, posters, abstracts, etc. PIs need to inform the BBVCTO when the study has met its endpoints and is considered complete.

- OSU-CVM intramural grant studies require annual reports during the research and a post-study completion report.
- Studies funded by non-profits and industry sponsors, will outline PI obligations for reporting indicated in the CTA.

3. Citing Research

The BBVCTO is considered a shared resource as it is supported by two NIH center grants. PIs utilizing BBVCTO or Biospecimen repository support are required to inform BBVCTO about clinical trials publications as these metrics are tracked for the NIH.

Key Point

- ALL publications need to cite the NIH CCTS grant UL1TR002733, and ALL cancer related publications need to also cite the NIH CCC grant P30 CA016058 in addition to the CCTS grant.

For other resources see **Appendix F**

APPENDIX A – OSP Sub-recipient Letter of Intent

THE OHIO STATE UNIVERSITY

Office of Research

Subrecipient Letter of Intent

Office of Sponsored Programs
1960 Kenny Road, Columbus, OH 43210-1016

To be completed by institution issuing the subaward:

Pass-Through Entity (PTE)

PTE PI Department	PTE PI Name		
Prime Sponsor	Solicitation No.	Performance Start	Performance End
Proposal Title			

A. Subrecipient Institution

To be completed by the subrecipient organization:

Subrecipient is a participant of the FDP Expanded Clearinghouse: ___ Yes *If yes, complete sections A-H then STOP. Return signed form.* ___ No *If no, complete the entire form, sections A-K, before returning.*

Institution's Legal Name			DUNS
Administrative Contact Name	Administrative Title	Administrative Email	Administrative Phone

B. Performance Site

Address			City
State	ZIP + 4	DUNS	Congressional District

C. Subrecipient PI

Subrecipient PI Name	Phone	Email	eRA Commons User Name *NIH proposals.*

D. Subrecipient Budget Request

Total $	Direct $	F&A $	Cost-sharing $ *Must be in budget & budget justification.*
Participant Support $: ☐ Yes ☐ No	Program Income: ☐ Yes ☐ No		Clinical Trial: ___ Yes ___ No

E. Compliance Information

Human Subjects: ☐ Yes ☐ No Vertebrate Animals: ☐ Yes ☐ No	Export Control: *Do you anticipate the use, transfer or development of items, software or technology that is export controlled?* ☐ Yes ☐ No ☐ Unknown at this time

F. Responsible Conduct of Research (RCR)

☐ If NSF, subrecipient institution certifies it maintains an institutional plan compliant with NSF's Responsible Conduct of Research requirement.

☐ If NIFA, subrecipient institution certifies it complies with NIFA's "Responsible and Ethical Conduct of Research" requirements.

G. Checklist of Proposal Documents Required

☐ Statement of Work	☐ Budget and Budget Justification	☐ Other _____

H. Subrecipient Approvals

The Authorized Official certifies the information on this form is accurate and complete and that the associated proposal has been reviewed and approved by the appropriate personnel of the subrecipient entity. The appropriate programmatic and administrative personnel involved in this proposal are aware of the sponsoring agency policies and are prepared to enter into an inter-institutional agreement consistent with those policies. Any work begun and/or expenses incurred prior to execution of a subaward agreement are at the subrecipient's own risk.

Authorized Official Name | Title

Signature of Authorized Official | Date Signed

Note: **FDP Expanded Clearinghouse Participants – STOP HERE** and Return Form. All Other Institutions Must Continue.

I. Subrecipient Institution

To be completed by the subrecipient organization:

Address	City	State	ZIP + 4	Congressional District

F&A rate agreement: ☐ Attached ☐ Link _____ | Institution Type: Select One From The Dropdown

Registered in SAM? ☐ Yes ☐ No | Check if Institution is: ☐ Less than or equal to 5 yrs. old ☐ HUB-Zone or Small Disadvantaged Business

J. Compliance Information

Human Subjects Assurance Number	Animal Welfare Assurance Number

K. Financial Conflict of Interest (FCOI) Compliance Statement

Check one.

☐ Subrecipient organization certifies that it has an active and enforced conflict of interest policy that is consistent with the provision of 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research."

☐ Subrecipient does not have a compliant conflict of interest policy but will develop one prior to issuance of a subaward. A model policy is available at the Federal Demonstration Partnership website.

☐ Subrecipient does not have a compliant conflict of interest policy and agrees to be bound by the conflict of interest policy of the issuing institution. (Ohio State url: orc.osu.edu)

☐ Not applicable - Non Public Health Service (PHS) funding.

APPENDIX B – CVM Facilities and Administrative (F&A) Policy

College of Veterinary Medicine
F&A Rates

The College of Veterinary Medicine incorporates the University's current policy for indirect costs. The below table is a list of F&A rates for common research sponsors.

Entity	IDC Rate
CVM Intramural Grants	10%
Industry	64.8%
Industry Clinical Trial	26%
Federal (NIH, CDC, NSF, etc.)	56%
Federal Clinical Trial	26%
NIH Fellowship (F-award)	0%
NIH Career Development (K-award)	8%
USDA/NIFA	42.857%
USDA/NIFA Fellowship	0%
Morris Animal Foundation (Fdn)	8%
Gates Foundation	10%
National Pork Board	0%
American Kennel Club Fdn	8%
American Veterinary Medical Fdn	8%
Winn Feline Foundation	0%
Other non-Industry Sponsor with no posted IDC cap	56%

A reduced F&A rate may be accepted on an exception basis. Please contact John Robinson or Dr. Patrick Green to discuss any deviation from these posted rates. It is helpful to provide a copy of the sponsor's written policy on F&A costs when requesting a deviation or submitting to a sponsor not listed above.

Facilities & Administrative (F&A) Costs

F&A costs are those costs associated with providing and maintaining the infrastructure that supports the research enterprise (buildings and their maintenance, libraries, etc.) and which cannot easily be identified with a specific project. The university encourages including the appropriate F&A costs in all proposal budgets, unless the sponsor specifically prohibits them, and it expects that F&A costs will be recovered to the maximum extent possible.

The university strives to maximize F&A cost recovery, consistent with sponsor policy (e.g., some federal agencies and not-for-profit organizations have a lower rate that they consistently ask awardees to accept). There may be instances when a department and college feel it is in their best interests to propose a rate lower than that which the sponsor routinely provides. Units can propose and accept lower rates; this should be a rare occurrence, however.

"Facilities" is defined as depreciation and use allowances, interest on debt associated with certain buildings, equipment and capital improvements, operation and maintenance expenses, and library expenses. "Administration" is defined as general administration and expenses, departmental and college

administration, sponsored projects administration, and all other types of expenditures not listed specifically under one of the subcategories of Facilities.

F&A cost rates are determined in conjunction with auditors from the U.S. Department of Health and Human Services. There are separate rates for different types of activities, but in each case the rate is calculated and charged as a percentage of modified total direct costs (MTDC). To determine the MTDC base to which the F&A rate will be applied, add all direct costs then subtract equipment, capital expenditures (alterations and renovations), charges for patient care and tuition remission, off-campus space rental costs, scholarships and fellowships, and the portion of each sub-grant or subcontract in excess of $25,000.

When a F&A rate lower than the appropriate university approved rate is used, the rate is applied to all direct costs (i.e., the base to which the F&A rate is applied is total direct costs, not modified total direct costs), unless the sponsor specifically excludes certain categories.

Facilities & Administrative (F&A) Costs on Subcontracts

If a project does not recover F&A costs at the appropriate negotiated rate, the F&A cost base is total direct costs (TDC), which includes the entire subcontract amount, unless the sponsor specifically excludes subcontract costs. In addition, any F&A cost restrictions are passed on to the subcontractor.

If a project recovers F&A costs at the appropriate negotiated rate, only the first $25,000 of the subcontract is subject to F&A costs. In a multiple-year project, the total subcontract amount across all years is considered in calculating the F&A costs. Thus, if organization X will receive a subcontract for $40,000 in each year of a four-year project, F&A costs are applied only to the first $25,000 in year 1. However, if the budget is $10,000/year, F&A costs would be applied to the entire subcontract amount for years 1 & 2; to $5,000 in year 3; and not at all in year 4.

F&A Cost Rates

Based on the University's current rate agreement, for projects funded on or after 07/1/18 the rates will be:

Activity	Period	On-Campus	Off-Campus*
Federal/Foundation Sponsored Research	7/1/18 – 6/30/2020	56%	26%
Instruction	7/1/16 – 6/30/2020	52%	26%

Rates are applied to a Modified Total Direct Cost (MTDC) base i.e., to all costs except equipment (stand-alone items with a useful life of a least 1 year and a unit cost of at least $5,000); alterations and renovations; patient care costs; tuition; rental of off-site facilities; subcontract and sub-grant costs in excess of $25,000.

*Off-campus rate applies to those projects (a scope of work or activity with a separate budget and accounting) for which 50% or more of the salary and wages are incurred in facilities not owned and controlled by the University and for which rent is allocated as a direct cost to the project.

APPENDIX C – Healthy Pets in Clinical Trials

Enrollment of healthy privately-owned animals as controls in clinical research is a necessary and frequent occurrence in the VMC.

- A *healthy animal* is defined as any privately-owned animal coming to the VMC solely to participate as a “control” or “normal animal” in a clinical research project or to donate “normal” fluid (blood, urine, etc.) or tissue for use in a research project.
- These animals do not have a disease process that requires treatment during their visit, and are presented to the VMC solely to participate in research at the request of clinicians/investigators
- A privately-owned animal is defined as any animal not owned by the University. Please note that faculty, staff, or student owned animals all fall into this category.

For animals that meet these criteria, the following guidelines should be observed:

- These studies require IACUC approval and an informed study consent form signed by the owner.
- Investigators are responsible for maintaining study binders or electronic data forms with signed consent forms.
- Animals should be placed on the appointment schedule of the managing service.
- Animals should not take up regular appointment slots; rather a drop off /add-on slot should be used to place the animal on the schedule.
- A medical record accession should be created for each visit the animal makes to the VMC.
- These patients require a physical exam documented in the medical record.
    - An examination charge should be entered into EzyVet in association with the animal’s visit.
    - Faculty, staff and student pets receive a $25 employee exam fee.
    - Non-employee/student pets receive the regular examination fee or recheck examination fee charged by the service.
- Animals should be housed in their respective service ward.
- A discharge summary should be created for each visit to the VMC and placed in the animal’s medical record. It may be brief but should include at a minimum
    - Name of the study the animal is participating in
    - Principal investigator
    - General description of the activities performed as part of the study
- After the discharge, any follow-up communications regarding the health status of the animal should be recorded in the communications log as well as the animal's study binder.

APPENDIX D – PI Leave Designation SOP

STANDARD OPERATING PROCEDURE		THE OHIO STATE UNIVERSITY VETERINARY MEDICAL CENTER	
Title:	PI Leave Designation SOP	Author:	BBVCTO Associate Director
Issued By:	BBVCTO & Office of Research	Version:	1.0
Date of Issue:	October 7, 2019	Revision Date:	December 10, 2019

Objective: This document will provide the guidelines and set expectations for Principal Investigators (PIs) who have in-hospital patients on a clinical trial and need to designate another clinician as a lead in their absence.

Purpose:

1. Provide clear and consistent expectations from PIs when they are on vacation or other approved e-leave and are unavailable to attend to their in-hospital clinical trial patients
2. Establish a secondary clinician who is responsible for trial-related procedures in the PI's absence.

Definitions

a. PI on leave – the designated official PI for a clinical trial is the person named in the contract with the industry, academia or government grants and on IACUC study team and owner informed consent form. *Leave* is defined as any amount of time a patient is in the hospital for the trial and the PI is not present or available to care for the animal. The designated individual has also signed a PI contract with the BBVCTO. When this person is not available to perform the responsibilities designated on the trial, the PI must have a secondary clinician, who has agreed to carry-out their duties. This person *must also be named* in the contract, on the grant or protocol, IACUC, the BBVCTO PI contract and the owner informed consent form. Clinical trial patients should not be scheduled when the PI is off- service and working remotely during the off-service time.

Responsibilities

Principal Investigators

a. Effective communication between the PI, the BBVCTO, and all services affected by the PIs absence is critical to support the operational needs of all faculty and staff involved, as well as to ensure appropriate care of the patient(s).
    i. All communication must be documented in an e-mail format. Verbal communication alone will not be accepted.
    ii. The PI will provide all necessary documents to secondary clinician for trial- related procedures and potential treatment protocols for minor adverse events.
    iii. The PI must be available *at all times* either by phone or e-mail in case of an emergency/serious adverse event.
        - If this is not possible, an emergency plan must be written down in the documents provided to secondary clinician.
        - The study sponsor or study monitor should be aware of this situation via e-mail and be asked if they can be available for care recommendations in case of any serious adverse events.
        - If a patient will require after-hours or weekend care, this will be communicated thoroughly by the PI via e-mail designating who is responsible for caring for these patients. This communication should be copied to the BBVCTO if they are involved with any aspects of the trial. The BBVCTO staff is not available to assist with weekend patient care.

b. The PI will review all protocol activities performed and clinical visit forms upon their return to ensure that appropriate actions were taken in their absence.

c. If the PI has a **planned** absence:
   i. As soon as the planned absence is known or at least 1 week prior to absence, an e-mail must be sent out to the service faculty members and resident/intern who is expected to take over care of any patients during the time of absence. This communication should include the study protocol, expected duties and plans if an adverse event should occur.
   ii. Once a secondary clinician for patient care is established and documented via e-mail, an additional e-mail notification then must be sent out to all support faculty and staff involved and to the BBVCTO Director/Associate Director if the BBVCTO is involved with the trial

d. If there is an **un-planned** absence (i.e. family emergency or illness)
   i. An e-mail will be sent as soon as possible to the applicable service: faculty, staff, and the BBVCTO (include Associate Director)
   ii. PI will designate an appropriate secondary clinician in this e-mail to take the lead on any patient(s) needing care in their absence.

Designated Secondary Clinician (Faculty, Resident, or Intern)

a. Once the designated secondary clinician has been established and this has been documented in an e-mail, all responsible for patient care must be in contact with their respective service members, BBVCTO staff and Associate Director to ensure exceptional care for patients.
   i. The secondary clinician will be provided a document from the PI describing in detail what their responsibilities are for the patient(s).
      - Secondary clinicians will not be permitted to deviate from any documented plan/protocol unless approved by the PI or study sponsor.
   ii. The secondary clinician will complete all required paperwork/clinical visit forms within 24-hours of seeing the patient.
      - This will be reviewed by the PI upon their return to ensure appropriate actions were taken.

BBVCTO Staff

a. E-mail communication to the BBVCTO staff and Associate Director are critical in ensuring that clinical trial protocols are being followed and that patient care is covered during the absence of the PI.

b. Once the e-mail is received from the PI and secondary clinician regarding dates/times that the PI will be absent, the Clinical Research Coordinator assigned to the study will schedule a time to meet with the secondary clinician and PI to ensure that protocols will be followed appropriately and to establish responsibility for those protocol activities.

c. BBVCTO staff (Clinical Research Coordinators) are not required to work weekends.
   i. If a patient will require weekend or after-hours care, that responsibility will fall onto the secondary clinician or will be designated by the PI prior to their absence.

APPENDIX E – Clinical Trial Material Retention Policy

STANDARD OPERATING PROCEDURE		THE OHIO STATE UNIVERSITY VETERINARY MEDICAL CENTER	
Title:	Clinical Trial Material Retention Policy	Author:	BBVCTO Associate Director
Issued By:	BBVCTO	Version:	1.0
Date of Issue:	11/8/19	Revision Date:	

Objective: This document provides guidelines for the length of time clinical research materials should be retained for BBVCTO managed studies and how to dispose of the materials following the end of the retention period. The BBVCTO will adhere to any retention periods outlined by industry-sponsored agreements.

Purpose:

1. Inform PIs and staff how long research materials should be kept dependent on study type.
2. Provide instructions on how to properly discard study materials dependent on the study type.

Definitions:

Retention Period: The period for which study materials are to be kept following the completion of a study.

Procedures:

1. Publications:
    a. Industry:
        i. Specified in the industry/sponsor contract.
        ii. Generally, the requirement is to keep study materials for 7 years post publication.
    b. Non-Industry:
        i. The requirement is to keep study materials for 2 years post publication.

    - All study materials will be securely disposed of and documented in the indicated spreadsheet located in the BBVCTO Shared drive.

2. Abstracts:
    a. Industry:
        i. Specified in the industry/sponsor contract.
        ii. Study materials will be kept for 7 years post the date the abstract was published.
    b. Non-Industry:
        i. Study materials will be kept for 3 years post the date the abstract was published.

    - The PI will be notified and the materials will be securely disposed of or returned to the PI or the sponsor. This will be documented in the indicated spreadsheet located in the BBVCTO Shared drive.

3. No Publication/Abstract:
    a. Industry:
        i. Specified in the industry/sponsor contract.
        ii. Study materials will be kept for 7 years post the close of the clinical trial.
    b. Non-Industry:
        i. Study materials will be kept for 3 years post the close of the clinical trial.

- The PI will be notified and the materials will be securely disposed of or returned to the PI or sponsor. This will be documented in the indicated spreadsheet located in the shared drive.

4. Consent Forms:
    a. All clinical trial paper consent forms that are identified to be securely disposed of will be saved by an electronic copy. All paper copies will be turned over to The Ohio State Veterinary Medical Center Medical Records Department for distribution into the patient medical record.
    b. For each clinical trial being disposed of the BBVCTO staff will scan in all consent forms as one PDF document per clinical trial.
    c. These PDF documents will be saved in the indicated clinical trial folder on the BBVCTO Shared drive.
    d. This will be documented in the indicated spreadsheet located in the VMC shared drive.

APPENDIX F – Useful links

- PI Effort Certification (e-Cert): Application used to comply with mandated effort certification
- CVM Shared Resources and Equipment
- Training-How to be a Principal Investigator
- Grant and Funding Opportunities
- Office of Sponsored Programs eTools: The (OSP) partners with faculty and staff to provide the highest quality research administration at all stages of sponsored projects, from identifying funding sources through award closeout.
- Research commons will work with faculty, researchers, and graduate students to help find grants and awards. Alternative sources of funding for research projects should first schedule an appointment with the college GSO (John Robinson).
- Statistical Consulting Services
  - VMAB Biostatistics Consult: Visit the Veterinary Medicine Academic Building, room 145 on Mondays from 8:00 am - 9:00 am for help on creating a testable hypothesis, study deign, data collection logistics, data management, and basic data analysis. Email Rebecca Garabed to set up an appointment.
  - The Center for Biostatistics: Provides fee for service collaborative support in all areas of biostatistical expertise, including study design, data management, and statistical analysis of clinical, epidemiological and laboratory research data for faculty, staff and students at the Ohio State University.
  - CCTS Biostatistics Consultation: Offers open office hours for biostatistics consultations. Statistics Course 5760: If the clinical trial is a resident or a master's student project, they can enroll in statistics 5760 and receive up to 17 hours of help from a graduate student consultant during the semester in which they are enrolled. Students may enroll up to five semesters. For more information visit https://scs.osu.edu/working-scs/students.
- Technology Commercialization Office (TCO): Helps researchers facilitate the translation of research and innovation into the market where it can have an impact on people and the economy. TCO also provides signatory and negotiation services on CDAs and MTAs.
- CCTS Voucher Support: The CCTS provides funding support to investigators who require assistance from a CCTS core, such as the BBVCTO to generate data for new or ongoing projects and/or secure fee-based core services for expert consultation with the ultimate goal of furthering clinical and translational research. A few examples of voucher support may include services from the BBVCTO, REDCap builds, support for accounting, genomics, and biostatical support.
- Animal imaging consortium: The MRI Facility was created as part of the Ohio Cellular and Molecular Imaging Consortium (OCMIC) with the goal to facilitate inter-institutional collaboration between Academic Institutions in Ohio and technology transfer to Industry.
- Comprehensive Cancer Center and Solove Research Institute (CCC): Offers a multidisciplinary team approach including Ohio State scientists and researchers from 14 colleges at The Ohio State University who have a research focus on cancer and translate basic, clinical and prevention research into quality cancer care.
- Drug Discovery Institute (DDI): Ohio State's DDI is uniquely structured to accelerate drug development projects by strategically investing funds and managing programs to reach key drug development milestones as quickly as possible.
- The Center for Clinical & Translational Science (CCTS): The CCTS provides tools and resources to help PIs in all aspects of a research project. The CCTS provides research consultation services designed to help faculty, staff and service providers manage their translational research projects.
- MyCCTS: PIs can requests CCTS consultation services, which is a service request system that spans across a spectrum of The Ohio State University service providers, such as Biomedical Informatics (BMI).
- Translational Therapeutics Think Tank –T4: The mission of the Translational Therapeutics Think Tank (T4) is to provide consultation and guidance for investigators working in novel drug/device discovery and development within The Ohio State University and Nationwide Children Hospital (NCH) communities.

T4 services: study design; drug, device, and biomarker development; ethical and regulatory issues; laboratory or clinical animal modeling and pathology; pharmacology; and toxicology/pathology. After providing a brief (5-10 minute) over-view of the project, the T4 group will engage in a discussion with the PI permitting brainstorming of early-stage projects, provide input to enhance the likelihood of success and assist in alignment with collaborators and other resources across.

- The Clinical and Translational Science Award One Health Alliance (COHA): COHA is comprised of veterinary schools partnered with medical and other colleagues through a National Institutes of Health Clinical Translational Science Award (CTSA). COHA's mission is to advance our understanding of diseases shared by humans and animals. The alliance leverages the expertise of physicians, research scientists, veterinarians, and other professionals to find solutions for medical problems and to address the well-being of humans, animals, and the environment. This approach capitalizes on One Health opportunities to accelerate translational research.