

## IACUC IR/TR/AME PRE-REVIEW GUIDE FOR INVESTIGATORS

Please use this guide as you work on your IR, TR, or AMEs. The sections are meant to capture the needed information for the committee to understand what all animals will experience on the protocol, as per federal regulations. **Please direct questions you have regarding the information in unshaded areas to Office of Animal Welfare Assurance staff. Questions regarding the information in yellow shaded areas should be directed to your CCM veterinarian.** Hopefully you find the included resources helpful, which are links to instructions, policies, or useful tools related to the information being requested.

OVERVIEW	
General	Confirm that all responses address the question asked, and all relevant checkboxes are checked.
	Confirm that all acronyms and abbreviations are defined at first use
	<b>For TRs only:</b> remove all references to previous amendments and be sure that the TR is a de novo standalone document that describes work to be done over the next 3-year approval period <ul style="list-style-type: none"> <li>clarify which previous aims have been completed</li> <li>add the new studies for the next 3-year approval period</li> <li>update animal numbers to reflect only the number needed for the next three years.</li> </ul>
	<b>For AMEs only:</b> <ul style="list-style-type: none"> <li>modify all protocol forms that are impacted by the proposed change</li> <li>modify the Experimental Design section of the relevant Research Objective form, the associated Flow Chart, and the Potential Pain and Distress form if animals are being added</li> <li>modify the Related Records page for all funding and sponsor changes</li> </ul>
Relevant Resources & Helpful Links	<ul style="list-style-type: none"> <li>➤ <a href="#">IACUC Protocol Review</a></li> <li>➤ <a href="#">Policy on Principal Investigator Eligibility</a></li> <li>➤ <a href="#">Amendment Review Process</a></li> </ul>

INITIAL SURVEY FORM	
Question B	If only part of the work will be done at MGH, the other institution and contact must be appropriately identified
	Outside institution IACUC protocol and/or approval must be uploaded
Relevant Resources & Helpful Links	<ul style="list-style-type: none"> <li>➤ <a href="#">Protocol Review Process</a></li> </ul>

TRIENNIAL REVIEW FORM	
Question 1	All information indicated by bullet points is included. Make sure that the number of in-house animals is reported on the Potential Pain and Distress form, as should be referenced here, and alluded to on other forms (e.g. Only breeding as source, so founders, etc).
Relevant Resources & Helpful Links	<ul style="list-style-type: none"> <li>➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel</li> </ul>

IACUC AMENDMENT FORM	
Question 1	State all changes that are being made via the amendment
	Provide an explanation if no additional animals are required
Question 2	Clearly state the reason for the proposed change(s) and provide adequate justification
<b>Relevant Resources &amp; Helpful Links</b>	➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel

PROTOCOL OVERVIEW FORM	
Question 1 and Question 2	The requested information should be presented in layman's terms
<b>Relevant Resources &amp; Helpful Links</b>	➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel ➤ <a href="#">Sample Protocols</a>

RESEARCH OBJECTIVE FORM	
Experimental Design (Section B)	All bullet points in the instructions are addressed
	All study aims, experimental approaches, experimental groups are clear; all acronyms and abbreviations are defined
	Sequence and timing of all procedures that comprise an experiment are included (reference to a procedure matches the name of the procedure form)
	Details regarding how a procedure is carried out (e.g. anesthesia regimen, pre-and post-operative analgesia, suture size etc.) are not included in this section
	If animal numbers and pain category assignments are included in this section, they must be consistent with the information presented on the flow chart
Flow Chart (Section C)	A single document comprising flow charts for all experiments described in Section B is uploaded here
	The flow chart is consistent with current IACUC standards outlined in the Flow Chart Preparation section found here: <a href="#">Flow Chart Preparation</a>
	The flow chart describes only those experiments related to the Research Objective; each objective has its own flow chart
	Animal numbers and pain category distribution reported on the flow chart are consistent with information presented on the Potential Pain and Distress form
	All previous versions of the flow chart are deleted from this section. It will require saving the new flow chart document with a different name than any other attachment associated with this protocol, attaching it to <i>Section C. Flow Chart of the Research Objective</i> , and then deleting any other documents from this section. <b>Flow charts should never be added or deleted through the Attachments tab</b>
Health Status (Section D)	<u>Question 1:</u> Describe what the animals will look like over the course of the experiment for each experimental group. Indicate the frequency of monitoring, including weighing
	<u>Question 1:</u> Attach clinical scoring systems or body condition scoring systems here
	<u>Question 1:</u> Do not include post-operative monitoring (that should be inserted in your response to Question 1 in Section E of the relevant procedure form)
	<u>Question 1:</u>

	Do not include post op analgesics (that should be inserted in your response to Question 2 in Section E of the relevant procedure form)
	<p><b>Question 2:</b></p> <p>If any of the symptoms described in your response to Question 1 appear, describe here what you will do. Do not include humane endpoints. Humane endpoints should be described in Section A of the Humane Endpoint, Disposition and Euthanasia form</p>
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel</li> <li>➤ <a href="#">Flow Chart Preparation</a></li> </ul>

<b>ANIMALS FORM</b>	
Question 1a	All strains/breeds are listed including ones being added through an amendment
Question 2	If the animals have a special phenotype, make sure that any specialized housing needs are captured on the MGH Housing form
Question 3	Confirm that animal source reported here is consistent with information provided elsewhere in protocol
	Identify the MGH protocol that will serve as a source of animals if animals are being transferred from another protocol
	Complete a Breeding Studies form if animals will be bred as part of the protocol
Question 4	Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for protocols proposing to study only one sex
Question 5	<p>The following identification methods require a procedure form:</p> <ul style="list-style-type: none"> <li>• Implant/Microchip</li> <li>• Ear Notch/Tag</li> <li>• Other/Toe Clipping</li> </ul>
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel</li> <li>➤ <a href="#">Policy on Animal Acquisition</a></li> <li>➤ <a href="#">Animal Ordering and Transfers</a></li> </ul>

<b>POTENTIAL PAIN AND DISTRESS FORM</b>	
General	Assigned pain categories are appropriate based on other forms (e.g. research objective, procedures etc)
	Numbers match those reported in other sections, especially the Flow Chart and Experimental Design section of the Research Objective form(s)
	Breeders and culled offspring are included
	<b>For TRs only:</b> animals in house at the time of submission (as reported on the Triennial Review form) are included in the table and animal numbers for completed experiments are removed
	<b>For AMEs only:</b> any additional animals required for the amendment are assigned to the appropriate pain and distress category.
Question 3	The response should be “Yes” if requesting extra animals for failure or training has been discussed on other forms
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ <a href="#">Guidelines for Assigning Pain and Distress Categories</a></li> <li>➤ <a href="#">Sample Size Calculations in Animal Research</a></li> <li>➤ <a href="#">ClinCalc Sample Size Calculator</a></li> <li>➤ <a href="#">Other Tools and Aids - Jackson Laboratories Breeding Colony Size Planning Worksheet</a></li> </ul>

REPLACEMENT REDUCTION REFINEMENT FORM	
Question 3b	Date of literature search is within 6 months of submission date
Question 3c	The surveyed time period is through the date of the literature search
Question 3d	All painful or distressful procedures or sequelae including those being added in an amendment are incorporated in the literature search
	Key words are appropriate and include surgical approaches and species

HUMANE ENDPOINT DISPOSITION AND EUTHANASIA FORM	
Humane Endpoints (Section A)	If your humane endpoints match the provided list, then select “Animals will be removed from the study and euthanized if any of the above clinical signs/conditions are found.” If the listed endpoints match your experiments but you also have model specific endpoints, those should be described in the text box. If one or more listed humane endpoints <b>do not match</b> your humane endpoints select “Some or all of the criteria listed above cannot be applied to this study. Animals will be euthanized if the following criteria are met” and describe deviation(s) in the text box. Contact your CCM veterinarian if you have questions about your humane endpoints
Moribundity and Mortality (Section B)	<u>Question 1:</u> If you choose “Yes” here, your justification should include the scientific rationale, what alternatives were considered and why morbidity as an endpoint cannot be used
	<u>Questions 4a and 4b:</u> The monitoring schedule must be appropriate for the model and it must increase when animals begin to exhibit signs of morbidity Those animals that are not expected to survive until the next scheduled evaluation should be humanely euthanized. Signs of moribundity selected must be relevant to the model
Animal Transfer and Disposition (Section C)	All checkboxes that correlate with information presented in other parts of the protocol are appropriately checked
	If transfer to another institution is checked, confirm that the response to Question B on the Initial Survey form is “Yes” and include a Transportation form
<b>Relevant Resources &amp; Helpful Links</b>	➤ <a href="#">Animal Export to an Outside Institution</a>
Euthanasia Method (Section D)	The checked euthanasia methods are consistent with information presented elsewhere in the protocol
	A separate procedure form is included when general anesthesia followed by non-survival surgery or exsanguination is checked
	The correct method of euthanasia by CO <sub>2</sub> overdose is selected, if using (e.g. Euthanex, use of secondary method)
<b>Relevant Resources &amp; Helpful Links</b>	➤ <a href="#">AVMA Guideline for the Euthanasia of Animals, 2020</a>

HOUSING MGH FORM	
CCM Centralized Facilities (Section IA)	Appropriate housing location is entered (e.g. a rodent facility is not entered for an NHP protocol)

Investigator Managed or Satellite /Lab Housing Areas (Section IB)	Scientific justification for laboratory housing is provided
Special Requirements (Section II)	Cross check any phenotype described on the Animals form to determine if special housing needs are indicated
	All specialized handling, husbandry, housing requirements described elsewhere in the protocol are appropriately checked (e.g. use of a medicated diet or metabolic cages, non-social housing)
	<b>For AMEs only:</b> any change to special requirements due to modifications being made in the amendment is documented
	The “No special housing or husbandry is required” option is unchecked if any other requirement is selected
	The “Other” option is checked only when none of the existing options is appropriate
Relevant Resources & Helpful Links	<ul style="list-style-type: none"> <li>➤ <a href="#">Policy on Housing of Live Vertebrate Animals Outside of CCM Centralized Facilities</a></li> <li>➤ <a href="#">Policy on Housing and Use of Animals Outside of MGH</a></li> <li>➤ <a href="#">Policy on Environmental Enrichment and Social Housing</a></li> </ul>

ANESTHESIA REGIMEN FORM	
General	There is a separate form for each anesthesia method discussed in other protocol sections
	Procedure bank forms available at this link are used whenever possible: <ul style="list-style-type: none"> <li>➤ <a href="#">Standard Anesthesia Regimens</a></li> </ul>
Question 1 (Agents)	Select anesthetics that minimize any pain or distress associated with handling or the induction of anesthesia, can be precisely titratable, do not interfere with the research goals and are compatible with available equipment, other medications, and staff training
Question 2 (Paralytics)	Due to the inherent difficulties in assessing the level of surgical anesthesia in paralyzed animals, the use of these drugs will be approved only if it is clearly established that (1) neuromuscular blockers are essential for the proposed research, and (2) that the investigator is able to monitor the animals appropriately for signs of pain and distress
Question 3 (Non-Pharmaceutical Grade)	If “No” is selected, make sure all non-pharmaceutical compounds are documented in Section B of the Controlled Substances and Non-Pharmaceutical Substance form
Question 4 (Depth of Anesthesia)	Select the criteria that will provide the best level of anesthesia monitoring given your regimen. If your species is a USDA covered species and the surgery this regimen will be used for is major, ensure you select those that have <i>major procedure</i> next to it
Question 5 (Frequency of Monitoring)	<p><b>Requirements:</b></p> <p>USDA-regulated non-rodent species: Depth of anesthesia must be assessed every 15 minutes, or more frequently as necessary</p> <p>All rodents: Animals will be monitored continuously with depth assessed at least every 15 minutes</p> <p>Non-mammals (fish, amphibians, reptiles, birds): Animals will be monitored continuously with depth assessed at least every 15 minutes</p>

Relevant Resources & Helpful Links	➤ <a href="#">Policy on Anesthesia and Analgesia</a>
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PROCEDURE FORM	
General	Check that there is a form that describes any procedure mentioned in other sections of the protocol
	<b>For TRs only:</b> remove any procedure forms that are no longer needed for the next approval period
	<b>For AMEs only:</b> check that all procedures being added have an appropriate procedure form
	Ensure the title makes sense and accurately captures what is being done
	Multiple procedures can be captured as one procedure form if they are performed as part of a single anesthetic event on the same animal
	Unnecessary or duplicated procedure forms are removed
	Separate procedure forms are not needed for multiple instances of the same procedure (e.g. IP injections or biopsy) when appropriate; different variations of the procedure can be described on the same form
	If the protocol contains a procedure bank form or a copied procedure form, make sure that the form has been properly edited to report all required and protocol-specific information including location where the procedure will be performed
	If you generate your own form to capture a standard procedure, make sure that form includes all standard procedure form elements
	Post-mortem surgeries do not require a procedure form
	A procedure form is included when general anesthesia followed by non-survival surgery or exsanguination is checked in Section D of the Humane Endpoint Disposition and Euthanasia form
	Use the procedure form as a checkpoint to ensure that other required forms (e.g. tumor or cell line use, restraint, controlled substances/non-pharma) forms are included
Procedure Type (Section A)	The correct procedure type is selected
	If the procedure is a survival surgery, it is correctly categorized as major or minor
	An appropriate procedure name is selected/entered
	Any Category D procedure is included in the literature search
Location (Section B)	Confirm that a building, room number and lab bench (if appropriate) has been entered
	When performing procedures in CCM facilities or Knight Surgical Research Lab (KSRL), enter the appropriate building and facility name rather than specific room numbers (e.g. Simches, CCM rodent facility; CNY 149, KSRL)
Preoperative procedures (Section C)	<b>Question 1 a – 1c:</b> See <a href="#">Policy on Surgery and Other Experimental Procedures</a> for requirements <b>Question 2:</b> Withdrawal of food is required for all anesthetic events in all species except rodents, frogs, and rabbits. Eye lubricant is required for all anesthetic events
Procedure (Section D)	An anesthesia regimen is included when necessary
	Duration of anesthesia is indicated
	Indicate pre-operative analgesic. See links below for species-specific pain management regimens

	<p>Indicate other medications to be given before induction of anesthesia. Be aware that anti-microbial use is not a substitute for proper aseptic technique, and all recovery surgery must be performed aseptically.</p> <p>The description of the procedure is clear and contains an adequate level of detail (e.g. surgical approach, closure method, dose, dosing frequency and duration of treatment for all administered agents, needle size, administered volume etc.)</p> <p><b>For AMEs only:</b> add all new administered experimental agents and include the relevant dose, dosing frequency and duration of treatment for each</p> <p>The procedure description includes euthanasia for terminal procedures</p> <p><b>Question 4a:</b> Indicate if this is tumor production procedure</p> <p><b>Question 4b:</b> Indicate location on body where tumor is injected or implanted and if the implantation is unilateral or bilateral</p> <p><b>Question 4c:</b> Indicate maximum size tumor will be allowed to grow. See <a href="#">Policy on Spontaneous and Induced Tumor Production in Rodents</a></p> <p><b>Question 5a:</b> Warming pad or blanket is recommended for most species and procedures</p> <p><b>Question 5b:</b> Animal maintains sternal recumbency – select for pigs, rabbits, and sheep Animal can sit upright – select for NHPs Animal is ambulatory – select for rodents Select “Other” for fish and frogs</p>
Post-operative/Post-procedural Care (Section E)	<p><b>Question 1:</b> See policy on <a href="#">Policy on Post-operative and Post-Procedural Care</a> Indicate here when sutures will be removed</p> <p><b>Question 2:</b> Indicate post-operative analgesics. See links below for species-specific pain management regimens</p>
Non-Pharma Grade Substances (Section F)	If “No” is selected make sure all non-pharma compounds are documented in Section B of the Controlled Substances and Non-Pharmaceutical Substance form
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ <a href="#">Standard Procedure Forms</a></li> <li>➤ <a href="#">Policy on Surgery and Other Experimental Procedures</a></li> <li>➤ <a href="#">Policy on Anesthesia and Analgesia</a></li> <li>➤ <a href="#">Pre and Post Operative Pain Management Levels for Mice and Rats</a></li> <li>➤ <a href="#">Anesthesia and Pain Management Regimens for Rabbits</a></li> <li>➤ <a href="#">Anesthesia and Pain Management Regimen for Swine</a></li> <li>➤ <a href="#">Anesthesia and Pain Management Regimens for Small Ruminants</a></li> <li>➤ <a href="#">Policy on Spontaneous and Induced Tumor Production in Rodents</a></li> <li>➤ <a href="#">Policy on Post-Operative and Post-Procedural Care</a></li> <li>➤ <a href="#">Policy on the Use of Non-Pharmaceutical Grade Substances in Laboratory Animals</a></li> </ul>

<b>MULTIPLE SURVIVAL PROCEDURES (SURGERIES) FORM</b>	
General	Check to see if the form is required based on the information provided in the Research Objective forms <b>For AMEs only:</b> update all details as necessary if a new sequence of survival surgeries is added
Question 1	The selected rationales are consistent with information provided in the Research Objective and relevant procedure forms
Question 2	Justification is provided for all sets of multiple survival procedures described in the protocol (e.g. one justification for osmotic pump implantation, replacement and removal and a separate justification for transplantation followed by multiple biopsies)
Question 3	The sequence and type of surgeries are correctly identified
Question 4	The sequence of surgeries and the timing between them are consistent with what is presented on the flow chart and in the Research Objective Experimental Design Section
Question 5	Indicate how you will determine if the animal is stable enough to undergo subsequent surgeries

<b>ADMINISTERED SUBSTANCE FORM</b>	
Hazard Type (Section A)	If either the need for a hazard form or the specific hazard type is unclear, contact the relevant Safety Ancillary Reviewer: <ul style="list-style-type: none"> <li>• <b>Biosafety</b> MGH Campuses: Carolina Sanchez-Cano <a href="mailto:csanchez-cano@mgh.harvard.edu">csanchez-cano@mgh.harvard.edu</a> 400 Tech Square/65 Landsdowne: Jessica Healey <a href="mailto:jhealey1@partners.org">jhealey1@partners.org</a></li> <li>• <b>Chemical Safety</b> MGH Campuses: Zachary McCarthy <a href="mailto:zmccarthy@mgh.harvard.edu">zmccarthy@mgh.harvard.edu</a> 400 Tech Square/65 Landsdowne: Justin Warrener <a href="mailto:jwarrener@mgh.harvard.edu">jwarrener@mgh.harvard.edu</a></li> <li>• <b>Radioisotope Safety</b> All: Nicholas Borges <a href="mailto:nborges@mgh.harvard.edu">nborges@mgh.harvard.edu</a></li> </ul>
Agent Administration (Section B)	Confirm that the reported dose, total number of doses, dosing frequency and time between administration and euthanasia (Questions 1 – 4) are consistent with the relevant procedure forms and flow chart
<b>Relevant Resources &amp; Helpful Links</b>	➤ <a href="#">MGH Manual of Safety Policies</a>

<b>CONTROLLED SUBSTANCE AND NON-PHARMACEUTICAL GRADE SUBSTANCE FORM</b>	
Controlled Substances (Section A)	<u>Question 2:</u> Storage location for controlled substances is identified
Non-Pharmaceutical Grade Substances (Section B)	<u>Question 1:</u> Check Section F of all relevant procedure forms to determine if non-pharma grade substances will be used
	<u>Question 2:</u> Confirm that the listed dose, duration, frequency, and administration route is consistent with the information presented in relevant procedure forms
	<b>For AMEs only:</b> include any newly added non-pharma grade compounds

	Confirm that the PI has signed the attestation
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel for the definition of a non-pharmaceutical grade substance</li> <li>➤ <a href="#">MGH Policy on Controlled Substance Use in Non-Human Research</a></li> <li>➤ <a href="#">Policy on the Use of Non-Pharmaceutical Grade Substances in Laboratory Animals</a></li> </ul>

<b>TUMOR AND CELL LINE USE FORM</b>	
General	Required when tumor production procedures are identified (e.g. injection/implantation of tumor cell lines) or non-tumor cell lines are administered (e.g. skin graft studies)
	Not required for spontaneous tumor models
	Separate forms are required for cell lines of each animal species; multiple cell lines from the same species can be detailed on a single form
	For AMEs only: added cell lines are captured on a new form or incorporated into a previously approved form
Question 2a	A Hazardous Agent Administration and Use form for human or NHP tumors/cell lines is included and those tumors/cell lines are identified as biological hazards
	Viral antibody test results for all tumors/cell lines of rodent origin produced outside of CCM have been attached
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ <a href="#">Animal Health &amp; Treatment</a> (see “Cell Lines”)</li> <li>➤ <a href="#">Policy on Spontaneous and Induced Tumor Production in Rodents</a></li> </ul>

<b>ADJUVANTS USE, ASCITES/ANTIBODY PRODUCTION FORM</b>	
Adjuvant Use (Section A)	<b>Question 1:</b> If Complete Freund’s Adjuvant (CFA) is used as the adjuvant, a chemical Hazardous Agent Administration and Use form is present
	<b>Question 2:</b> Reported use of CFA is consistent with information presented elsewhere in the protocol
Production of Antibodies (Section B)	Confirm that there are separate procedure forms for all selected blood collection methods
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ <a href="#">Policy on Adjuvant Use in Research Animals</a></li> <li>➤ <a href="#">Policy on Monoclonal Antibody Production</a></li> </ul>

<b>CONTROLLED FOOD OR FLUID INTAKE FORM</b>	
General	Not required for pre-procedural or pre-operative short-term restriction when withdrawal of food is checked on the relevant procedure form
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ <a href="#">Policy on Food and Fluid Restriction in Laboratory Animals</a></li> </ul>

<b>RESTRAINT AND DEVICE ACCLIMATION FORM</b>	
General	Form is present if restraint is described elsewhere in protocol
	Details reported on form are consistent with other sections of the protocol

<b>Relevant Resources &amp; Helpful Links</b>	➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel
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<b>BREEDING STUDIES FORM</b>	
Question 1	Response is consistent with the current <a href="#">Policy on Rodent Breeding and Cage Density</a>
Question 2	The following identification methods require a procedure form: <ul style="list-style-type: none"> <li>• Ear Notch/Tag</li> <li>• Other/Toe Clipping</li> </ul>
Question 4	The following genotyping methods require a procedure form: <ul style="list-style-type: none"> <li>• Ear Notching or Punching</li> <li>• Tail Snipping</li> <li>• Toe Clipping</li> </ul>
	The following genotyping methods require justification: <ul style="list-style-type: none"> <li>• Tail Snipping of Mice Greater Than or Equal to 21 Days of Age</li> <li>• Toe Clipping Under 7 Days of Age</li> </ul>
Question 5	Select “Other” if you are not using one of the listed pre-approved colony management systems
	<b>Question 5b:</b> Provide an explanation for why the alternative system must be used
	<b>Question 5c:</b> Upload a copy or screen shots of the system to confirm that it meets CCM requirements for colony management
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ The <b>PAGE INSTRUCTIONS</b> in the RIGHT navigational panel</li> <li>➤ <a href="#">Standard Procedure Forms</a></li> <li>➤ <a href="#">Policy on Rodent Breeding and Cage Density</a></li> <li>➤ <a href="#">Policy on Toe Clipping of Mice</a></li> <li>➤ <a href="#">CCM Rodent Colony Management Spreadsheet</a> (see CCM Seminars and Workshops under “Useful Links”)</li> <li>➤ <a href="#">Components Required for a Colony Management System</a> (see CCM Seminars and Workshops under “Useful Links”)</li> </ul>

<b>TRANSPORTATION FORM</b>	
General	Required even when moving animals between MGH facilities
Question 2	Biosafety Level 2 is checked when NHPs are being transported
<b>Relevant Resources &amp; Helpful Links</b>	➤ <a href="#">Policy for Transportation of Animals</a>

<b>STAFF FORM</b>	
General	Confirm that all staff members have current OHS clearance and have completed all required CITI modules
	Add Knight Surgical Research Laboratory (KSRL) as staff when you are performing procedures in their facilities
	Confirm that each procedure/responsibility listed in the Personnel Activity Grid has been assigned to at least one Study Staff member

	<p><b>For TRs only:</b></p> <ul style="list-style-type: none"> <li>• staff has been updated (e.g. staff who have left MGH are removed from the protocol)</li> <li>• review the Qualifications and Experience information for each individual and update as necessary</li> </ul>
	<p><b>For AMEs only:</b></p> <ul style="list-style-type: none"> <li>• confirm that all newly added procedures have been assigned to appropriate Study Staff members</li> <li>• check that CITI training requirements for all Study Staff have not changed after adding new procedures</li> </ul>
	Designate a Contact(s) for the protocol if appropriate
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ <a href="#">CITI Training and Occupational Health Requirements</a></li> <li>➤ <a href="#">Staff Guide</a></li> <li>➤ <a href="#">How to Sign Off on Your Study Staff Certification</a></li> </ul>

<b>ATTACHMENTS FORM</b>	
General	<b>Flow charts should only be added and removed through Section C of the Research Objective form and never through the Attachments tab</b>
	Confirm that any attachments referenced in the protocol are included (e.g. medication list)
	<b>For AMEs only:</b> update any attachment (i.e. medication list) that is impacted by the changes being made in the amendment
	If the protocol involves collaboration with an outside institution, confirm that the collaborator's currently approved protocol and IACUC approval letter are attached

<b>RELATED RECORDS FORM</b>	
Linked Agreements and Funds	<b>Note:</b> It is not necessary to link an active fund prior to IR/TR submission but animals cannot be ordered until an active agreement is added either during the IR/TR review process or via amendment following IR/TR approval
	Removal of expired/inactive funds is suggested
Linked Registrations	If biosafety hazards are being used in the protocol, confirm that an active IBC is linked and there is consistency between the IBC registration and IACUC form including personnel, room locations and hazards used in animals
	<p><b>For AMEs only:</b></p> <ul style="list-style-type: none"> <li>• Review the experiments being added and determine if you need to generate a new Biosafety Registration or make changes to your existing IBC (i.e. addition of a biological agent that is not currently approved by the IBC, using a biological reagent in a location that is not identified in your IBC)</li> </ul>
<b>Relevant Resources &amp; Helpful Links</b>	<ul style="list-style-type: none"> <li>➤ <a href="#">Add Funding Source Guide</a></li> </ul>

v1.1, 22 June 2021  
v1.2, 14 September 2021  
v1.3, 04 November 2021  
v1.4, 26 January 2023