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| --- | --- | --- | --- |
|  | Diagram  Description automatically generated |  | **FORM - Funding Verification and Activation** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Principal Investigator or Grant/Contract:** |  | | |
| **Name of Post-Award Admin:** |  | **Post-Award Admin Phone:** |  |
| **Grant/Contract Title:** |  | | |
| **Project Title (if different from Grant/Contract Title):** |  | | |
| **Name of Funding Agency:** |  | | |
| **Funding Source assigned agency number (e.g., R01 CA123456-01):** |  | **Dates of support if known Grant / Subaward/ Contract:** | to |
| **Is this a subaward?** | Yes → Prime award issued to (e.g., UW):  No | | |
| **Is this a supplement or pilot under an existing award?** | Yes →  Supplement  Pilot  No | | |
| **Name of Sponsored Research Officer handling award activation:** |  | **Funding Proposal ID # (e.g., FP50001864)** |  |

**The Office of Sponsored Research cannot activate awards until the Institutional Review Office (IRO) confirms that all necessary IRB and/or IACUC approvals are in place (not pending), including approval of the addition of funding. Please ensure all IRB and/or IACUC approvals are in place before you submit this form to the IRO.**

Review the IRB [Funding Verification and Activation](https://extranet.fredhutch.org/u/iro/funding/funding-verification-and-activation.html) webpage or contact [IRO@fredhutch.org](mailto:IRO@fredhutch.org) with questions about this process.

# Section 1: Scope of Work

1. Has the most current version of this grant/contract been submitted for IRB and/or IACUC review?

Yes → Go to [Section 2](#_Section_2:_Humans).

No → Stop. IRB and/or IACUC review and approval of the most current version of this grant/contract are required **before** activation. Do not submit this form if review is pending.

N/A → IRB and IACUC review are not required for this grant/contract. Answer Questions 1.a. and 1.b. **Submit a full copy of the grant/contract.** 

1.a. Indicate the reason IRB review is not required for this grant/contract. The activity described within this grant/contract:

Does not involve humans or human data/specimens → Go to Question 1.b.

Is Not Human Research (NHR) and all sources are on the [IRB Pre-Reviewed Sources of De-identified Human Specimens and/or Data List](https://extranet.fredhutch.org/u/irb/submissions-to-the-irb/research-not-involving-human-subjects.html#prereviewed) → Go to [Section 2](#_Section_2:_Humans).

Is non-exempt human subjects research, but Fred Hutch as an institution is not [engaged](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) → Go to [Section 5](#_Section_5:_Investigator).

1.b. Indicate the reason IACUC review is not required for this grant/contract. The activity described within this grant/contract:

Does not involve any animals or animal data/tissue → Go to [Section 5](#_Section_5:_Investigator).

Only involves non-regulated species of animals (e.g., fruit flies, nematodes, etc.) → Go to [Section 5](#_Section_5:_Investigator).

Only involves the use of animal data → Go to [Section 5](#_Section_5:_Investigator).

Only involves the use of animal tissue → Go to [Section 4](#_Section_4:_Animal).

# Section 2: Humans

1. Does this grant/subaward/contract involve Humans or Human Data/Specimens (e.g., interventions or interactions, human tissue, data derived from humans, access or use of medical records, use of human cell lines, etc.)?

Yes → Answer Questions 2.a, 2.b, and 2.c.

No → Go to [Section 3](#_Section_3:_Vertebrate).

2.a. Did the human activity funded by this grant/contract qualify as “Not Human Research” (NHR)? *(Check all that apply)*.

Yes → All sources are on the [IRB Pre-Reviewed Sources of De-identified Human Specimens and/or Data List](https://extranet.fredhutch.org/u/irb/submissions-to-the-irb/research-not-involving-human-subjects.html#prereviewed). Please identify source(s):

Yes → List the NHR Determination number: 6007-      **or** FHIRB

No → This research does not qualify for an NHR determination → Go to Question 2.b.

2.b. Does this grant/contract involve human subjects work overseen by the Fred Hutch IRB?

Yes → This grant includes “Delayed Onset” research without definitive plans for human subjects involvement. IRB Approval is required prior to any involvement of human subjects in research. (NOT-OD-12-130)

Yes → List all Fred Hutch IRB protocols supported by this grant/contract.

Per 45 CFR Part 46.118, the IRB is responsible to review and approve any funding source (grant/contract) for the research activity it supports. This review and approval must take place **before** the Office of Sponsored Research (OSR) can activate the funding.If you have not already done so, submit a Modification in Hutch to add this grant/contract to each file listed below.

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| --- | --- | --- |
| **FHIRB#** | **Approval From** | **Approval To** |
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No → Go to Question 2.c.

2.c. Does this grant/contract involve human subjects work where Fred Hutch is relying on an external IRB?

Yes → List all IRB protocols supported by this grant/contract.

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| --- | --- | --- | --- |
| **FHIRB#** | **External IRB**  **Tracking #** | **Approval From**  **(Determined by External IRB)** | **Approval To**  **(Determined by External IRB)** |
|  |  |  |  |
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No → Go to [Section 3](#_Section_3:_Vertebrate).

# Section 3: Vertebrate Animals

1. Does this grant/contract involve the use of live vertebrate animals at Fred Hutch or any other site, during any part of the project?

Yes → Answer Questions 3.a, 3.b, and 3.c.

No → Go to [Section 4](#_Section_4:_Animal).

3.a. Does this grant/contract involve the use of live vertebrate animals at Fred Hutch (*excluding* antibody production under IACUC Protocol ID PROTO20240028)?

Yes → This grant includes “Delayed Onset” animal activities that will not occur until year 2 or later in the award period as part of the research design described in the grant application or contract proposal (e.g., the initial development of a drug or device with subsequent animal testing projected into the future). IACUC review will be requested in subsequent years. (NIH FAQ <https://grants.nih.gov/grants/olaw/faqs.htm#647>)

Yes → List all Fred Hutch IACUC protocols supported by this grant/contract.

Per PHS Policy (IV, D) and NIH Grants Policy (Part II, Terms and Conditions), the IACUC is responsible to review and approve any new funding source document (grant/subaward/contract) for the research activity it supports.

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| **IACUC Protocol ID** | **Approval From** | **Approval To** |
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No → Go to Question 3.b.

3.b. Does this grant/contract involve the use of live vertebrate animals at an external (non-Fred Hutch) site as part of this project?

Yes → List all IACUC protocols supported by this grant/contract below. Attach confirmation that the performance site has completed a funding congruency check. 

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| **Fred Hutch Protocol ID** | **Performance Site Protocol ID** | **Approval From** | **Approval To** |
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No → Go to Question 3.c.

3.c. Does this grant/contract involve the production of custom antibodies?

Yes → Custom antibody production will be done at Fred Hutch through Shared Resources.

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| --- | --- | --- |
| **IACUC Protocol ID** | **Approval From** | **Approval To** |
| PROTO202400028  (Monoclonal Antibody Production in Small Rodents) | [*To be completed by IRO staff]* | *[To be completed by IRO staff]* |

The PI of PROTO20240028, as a vendor supplying custom antibodies to investigators, is responsible for all funding review and tracking. The award specified on this form does not need to be listed on PROTO20240028.

Yes → Custom antibody production will be done at a location other than Fred Hutch (e.g., R&R Research, LLC). Describe:

|  |  |
| --- | --- |
| Offsite Source Name: |  |
| Offsite Source Assurance #: |  |
| Offsite Source Project Specific Approval Date: |  |

Producing custom monoclonal or polyclonal antibodies at a location other than Fred Hutch does not require review and approval by the Fred Hutch IACUC. However, the location producing the antibody must have a current Assurance number with OLAW.

Antibodies are considered customized if produced using antigen(s) provided by or at the request of the investigator (i.e., not purchased off-the-shelf).

For a list of assured institutions, go to <http://grants.nih.gov/grants/olaw/olaw.htm>

No → Go to [Section 4](#_Section_4:_Animal).

# Section 4: Animal Tissues (not “live vertebrate animal” work)

4. Does this grant/contract involve the transfer of animal tissue to Fred Hutch?

Yes → Tissue Transfer Form Request #

Note: If this award involves the transfer of animal tissue from Fred Hutch to an outside institution, please contact BD&S at [mta@fredhutch.org](mailto:mta@fredhutch.org) to establish a materials transfer agreement (MTA).

No

# Section 5: Investigator Statement and Signature

As Principal Investigator, I certify that research activities involving human subjects or live vertebrate animals will not be initiated under this award without the grant/subaward/contract receiving appropriate IRB/IACUC review and approval. If the scope of work outlined in this award changes, a *Modification/Protocol Amendment* will be submitted to the IRB/IACUC. If in the future the award is used to support additional IRB/IACUC files, the grant/subaward/contract will be submitted for review and approval for the additional IRB/IACUC files before research activities funded by the grant/sub-award/contract commence.

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|  |  |  |  |  |
| Signature of Principal Investigator |  | Printed Name |  | Date |