

How OSRS checks an IRB or IACUC Approval

HUMAN SUBJECTS (IRB)

Washington University in St. Louis
Human Research Protection Office

Barnes Jewish Hospital
St. Louis Children's Hospital
Washington University

IRB ID #: <Reference No.>
To: <PI Name>
From: The Washington University in St. Louis Institutional Review Board,
WUSTL DHHS Federalwide Assurance #FWA00002284
BJH DHHS Federalwide Assurance #FWA00002281
SLCH DHHS Federalwide Assurance #FWA00002282
Re: <Protocol Title>

Approval Date: <Approved From Date>
Next IRB Approval Due Before: <Approved To Date>

Type of Application: New Project
 Continuing Review
 Modification

Type of Application Review: Full Board: Meeting Date: <Meeting Date>
 Expedited
 Exempt
 Facilitated

Approved for Populations: Children
 Signature from one parent
 Signature from two parents
 Prisoners
 Pregnant Women, Fetuses, Neonates
 Wards of State
 Decisionally Impaired

Source of Support: <Source (Sponsor)>
<Project Title>

NOTE: See Appendix A for specific details based on grant type or sponsor (e.g., outgoing subagreement, PPGs, fellowships).

- **To:** This should be the grant PI's name.
 - If not, confirm the 'Name of PI on Grant' in the 'Funding' tab of myIRB against the IRB approval 'Source of Support'. See "Checking in myIRB" for instructions.
- **Approval Date:** This is the date of the latest approval (or modification) for a protocol. For preaward, this is not necessarily the valid approval date. The valid approval date to use in a proposal is the date one year before the "Next IRB Approval Due Before" date (see next bullet).
- **Next IRB Approval Due Before:** This is the IRB approval expiration date. The initial IRB approval date is generally 12 months prior to this date. The grant or increment start date should not be after this date.
- **Source of Support:** This should list the Sponsor and grant title (or agency number) for the application/award.

How OSRS checks an IRB or IACUC Approval

NOTE 4/4/19 – HRPO will start process to include “Name of PI on Grant” in the IRB approval “Source of Support” section.

- If grant is not included in “Source of Support”, contact the DA for an updated IRB approval.
- Internal process:
 - Pre-award: If the application includes an IRB approval number/date, OSRS needs to see a copy of the applicable approval(s) before the application goes out, or submit the application with the approval as “pending”.
 - Award: OSRS needs the approval(s) prior to setting up the fund, or a completed and signed “Pending IRB Approval Letter”.
 - For any additional concerns/questions, elevate to your manager.

How OSRS checks an IRB or IACUC Approval

Checking in myIRB

1) Using the following link, log into the myIRB system with your WUSTL key:

<https://myirb.wusm.wustl.edu/>

2) Look up the protocol using IRB Reference No.



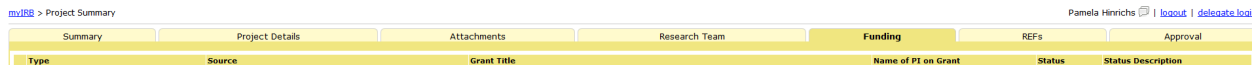
myIRB Authorization Error



- If you look up an IRB approval number in myIRB and get the following message, either:
 - You do not have access in myIRB
 - Notify your manager
 - There are no grants associated with the project within myIRB
 - Contact the DA for the IRB approval. Once received, confirm the grant is listed in the “Source of Support” on the approval.

3) After the protocol record is pulled up:

- a. You can go to the “Funding” tab for a list of grants and grant PIs associated with the protocol, or



- b. You can go to the “Attachments” tab to confirm grant applications associated with the protocol. These attachments will be in the Category “Grant from funding source or private foundation/association”. Note: Effective 1/21/2019, HRPO no longer requires a copy of the grant application. (Note to OSRS: This

How OSRS checks an IRB or IACUC Approval

step can be deleted in February 2020 as all grandfathered IRBs will have expired.)


Summary	Project Details	Attachments	Research Team	Funding	REFs	Approval
---------	-----------------	-------------	---------------	---------	------	----------

Project Attachments - IRB ID #: 201400014

Category	Ver
Consent & Assent Forms	12
Consent & Assent Forms	50
Grant from funding source or private foundation/association	1
Grant from funding source or private foundation/association	1
Grant from funding source or private foundation/association	1
Grant from funding source or private foundation/association	1
Grant from funding source or private foundation/association	1
Grant from funding source or private foundation/association	1
Notice of Just in Time (JIT) Documentation	1

How OSRS checks an IRB or IACUC Approval

Laboratory Animals (IACUC)

 Washington University in St. Louis

Institutional Animal Care and Use Committee

Animal Welfare Assurance # A-3381-01
<Approved Date>

To: <PI Name>
From: Brian Finck, Ph.D., Chair
Subject: Approval of Protocol for Experiments Utilizing Animals

Funding

Agency/Title: <Sponsor (or Originating Sponsor) / Award No.>
<Project Title>
<Fellow Name (if applicable) >

The Institutional Animal Care and Use Committee of Washington University has reviewed this protocol for the use of animals in conjunction with the research project named above. Federal laws and guidelines require that institutional animal care and use committees review ongoing projects annually. For the first two years after initial approval of this protocol, you will be asked to submit an annual progress report describing any changes in this protocol.

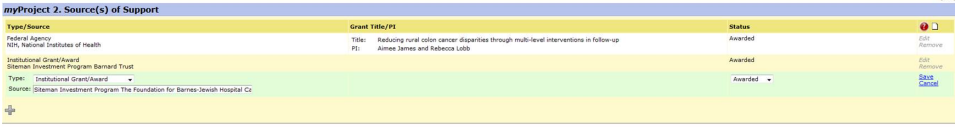
Approval Date: <Approved From Date> Approval No. <Reference No.>
Expiration Date: <Approved To Date>
Approved with Addendum
SPECIES:
Mouse

NOTE: See Appendix A for specific details based on grant type or sponsor (e.g., outgoing subagreement, PPGs, fellowships).

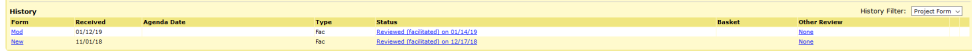
- **To:** This should be the grant PI's name.
- **Approval Date:** This is the date of the latest approval (or modification) for a protocol.
- **Expiration Date:** This is the IACUC approval expiration date. The initial IACUC approval date is generally 3 years prior to this date. The grant or increment start date should not be after this date.
- Internal process:
 - **Pre-award:** If the application includes an IACUC approval number/date, OSRS needs to see a copy of the applicable approval(s) before the application goes out, or submit the application with the approval as "pending".
 - **Award:** OSRS needs the approval(s) prior to setting up the fund, or a completed and signed "Pending IACUC Approval Letter". OSRS will not just prohibit 57 in the profile.
 - For any additional concerns/questions, elevate to your manager.
- The PI's department should contact IACUC to complete and submit an "Additional Sources of Funding" to add a grant to a protocol.

How OSRS checks an IRB or IACUC Approval

Appendix A

Types of Projects	Do PI, grant title or agency number need on IRB/IACUC approval need to match the grant?
Private Foundation Grants (e.g. Children’s Discovery Institute (CDI)/The Foundation for Barnes-Jewish Hospital (BJHF))	<p>IRB: If the person entering the protocol in myIRB selects Type/Source -> “Institutional Grant/Award” or “Other”, there is not an option to enter a project title. Per HRPO, DAs should not select this Type for such grants. Contact HRPO in these cases so they can contact the DA to fix it.</p> 
Incoming Subagreements	The Source of Support can be either the Sponsor or Originating Sponsor.
Outgoing Subagreements	<p>IRB: If WU is prime and human research is being performed <u>only</u> at the sub site, both WU and the sub need IRB approvals. Since WU is prime, we would also need an IRB approval (per Jeanne Velders on 6/5/19). IACUC: If WU is prime and animal research is being performed <u>only</u> at the sub site and WU is not purchasing and/or housing animals, we can accept IACUC approval letter from the sub site, but notify the WU IACUC so that they can establish an animal welfare MOU between WU and sub site (per Meredith Moore on 9/6/2019).</p>
Individual Training Grants (Fellowships, e.g., F31, F32)	<p>IACUC: Approvals will often be in Mentor/Sponsor name with either: 1) a footnote that fellow is approved to use the protocol or 2) the fellow is listed with the grant in the Funding section of the IACUC. Approvals in the fellow's name are acceptable. IRB: Approval will be in the name of the mentor.</p>
Program Projects/ Cooperative Agreements (e.g. P01, P30, P50, U01, UH2)	IACUC and IRB: Need approval(s) for each project or core that involves humans and/or animals. It is acceptable if the approval has the agency number of the grant, the grant title or grant acronym. PI on the protocol will be that of the individual project/core.
Individual Career Awards (e.g. K08)	IACUC and IRB: Approvals should be in the name of the PI (not the mentor).
Institutional Training Grants (e.g. T32)	IACUC and IRB: At preaward "indefinite" can/should be listed on the face page and protocols only need to be provided if agency asks for them. PI

How OSRS checks an IRB or IACUC Approval

	name on the approvals will be of the mentor/sponsor and titles do not need to match.																												
Institutional Career Awards (e.g. K12, K30)	<u>IACUC and IRB:</u> Need approval(s) for each scholar/allocation that involves humans and/or animals. It is acceptable if the approval has the agency number of the grant, the grant title or grant acronym. The scholar should be PI on the approval.																												
Projects with Pilot & Feasibility (P&F) Studies	<u>IACUC and IRB:</u> Need approval(s) for each project that involves humans and/or animals. It is acceptable if the approval has the agency number of the grant, the grant title or grant acronym. PI on the protocol will be that of the P&F.																												
Central IRB (cIRB)/Single IRB (sIRB)	<p><u>IRB:</u> In some instances, a WU IRB approval is not the IRB of record. OSRS needs to confirm HRPO has reviewed the IRB of record. The DA should provide a WU IRB # and the IRB of record. OSRS checks in myIRB that the IRB of record is linked to the grant.</p> <p>In myIRB, Summary tab should show 'Status' is Reviewed. There won't be an WU IRB approval document, but grant PI and Title should be listed on Funding tab.</p>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="7">History</th> </tr> <tr> <th>Name</th> <th>Received</th> <th>Agenda Date</th> <th>Type</th> <th>Status</th> <th>Basket</th> <th>Other Review</th> </tr> </thead> <tbody> <tr> <td>Bob</td> <td>01/12/19</td> <td></td> <td>Fac</td> <td>Reviewed (Fac/Inst) on 01/16/19</td> <td></td> <td>None</td> </tr> <tr> <td>Bob</td> <td>11/01/18</td> <td></td> <td>Fac</td> <td>Reviewed (Fac/Inst) on 11/21/18</td> <td></td> <td>None</td> </tr> </tbody> </table>	History							Name	Received	Agenda Date	Type	Status	Basket	Other Review	Bob	01/12/19		Fac	Reviewed (Fac/Inst) on 01/16/19		None	Bob	11/01/18		Fac	Reviewed (Fac/Inst) on 11/21/18		None
History																													
Name	Received	Agenda Date	Type	Status	Basket	Other Review																							
Bob	01/12/19		Fac	Reviewed (Fac/Inst) on 01/16/19		None																							
Bob	11/01/18		Fac	Reviewed (Fac/Inst) on 11/21/18		None																							
Allocations (non PPG, non-training, non inst.)	<u>IACUC and IRB:</u> If funds to be allocated involve the use of humans and/or animals, it is the Principal Investigator's responsibility to ensure that approved protocols are current.																												