**Managing IRB Review and Oversight**

**NEW: Amendments for Exempt Studies**

One-time fees are now required for studies that are exempt from federal regulations. To avoid non-compliance, here are some tips which may help:

- Remember to submit your studies at least 30 days prior to their expiration date.
- Use the Kuali system to help with the renewal process.
- Keep track of all file sizes for documents to be submitted to OIA.
- Submit a renewal of Business Systems accounts to OIA.

**NEW: Action Item Functionality**

A new Kuali KBAs for all of UCSD research can be found in the renewal application.

**NEW: IRB Fee Update**

OIA currently charges three fees to UCSD investigators as described on our Review Fees page. In light of the fact that these fees have not been evaluated in over five years, OIA was asked to re-evaluate our fees.

- **Funding Streams:**
  - A one-time fee for using a commercial external IRB (e.g., WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and is not required for studies funded by the UCSD/RCHSD. The one-time fee will be implemented for funded studies where the UCSD/RCHSD is engaged in the human subjects research.
  - A one-time fee will be implemented for funded studies where the UCSD/RCHSD is not engaged in the human subjects research. The one-time fee for using a commercial external IRB (e.g., WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and is not required for studies funded by the UCSD/RCHSD. The one-time fee will be implemented for funded studies where the UCSD/RCHSD is not engaged in the human subjects research.

**NEW: Action Item Functionality**

- The answers to these questions are: yes, no, and sometimes (respectively).
- If you want to discuss an Action Item with the analyst before resubmitting, please contact our general inbox at contact@irb.ucsd.edu. Remember that this is not a real-time chat feature. Entering a reply to an Action Item on your next submission will not alert the analyst that there may be a question or response.

**NEW: Max File Size for Kuali IRB**

- To accommodate the IRB without charge. None of the above fees apply to unfunded studies.
- Since access to Kuali is controlled through IT systems, some folks (RCHSD staff) have to obtain business systems accounts to be able to access certain parts of the system. This includes community clinics, other academic institutions, and other organizations for which the UCSD IRB is asked to provide IRB review and oversight.

**NEW: IRB Fee Update**

- A one-time fee for using a commercial external IRB (e.g., WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and is not required for studies funded by the UCSD/RCHSD. The one-time fee will be implemented for funded studies where the UCSD/RCHSD is not engaged in the human subjects research.
- A one-time fee for using a commercial external IRB (e.g., WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and is not required for studies funded by the UCSD/RCHSD. The one-time fee will be implemented for funded studies where the UCSD/RCHSD is not engaged in the human subjects research.

**NEW: Action Item Functionality**

- The answers to these questions are: yes, no, and sometimes (respectively).
- If you want to discuss an Action Item with the analyst before resubmitting, please contact our general inbox at contact@irb.ucsd.edu. Remember that this is not a real-time chat feature. Entering a reply to an Action Item on your next submission will not alert the analyst that there may be a question or response.

**NEW: Max File Size for Kuali IRB**

- To accommodate the IRB without charge. None of the above fees apply to unfunded studies.
- Since access to Kuali is controlled through IT systems, some folks (RCHSD staff) have to obtain business systems accounts to be able to access certain parts of the system. This includes community clinics, other academic institutions, and other organizations for which the UCSD IRB is asked to provide IRB review and oversight.

**NEW: IRB Fee Update**

- A one-time fee for using a commercial external IRB (e.g., WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and is not required for studies funded by the UCSD/RCHSD. The one-time fee will be implemented for funded studies where the UCSD/RCHSD is not engaged in the human subjects research.
- A one-time fee for using a commercial external IRB (e.g., WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and is not required for studies funded by the UCSD/RCHSD. The one-time fee will be implemented for funded studies where the UCSD/RCHSD is not engaged in the human subjects research.

**NEW: Action Item Functionality**

- The answers to these questions are: yes, no, and sometimes (respectively).
- If you want to discuss an Action Item with the analyst before resubmitting, please contact our general inbox at contact@irb.ucsd.edu. Remember that this is not a real-time chat feature. Entering a reply to an Action Item on your next submission will not alert the analyst that there may be a question or response.