GUIDANCE: Determining Study Review Type from Legacy eIRB System

In figuring out when and how to rollover a current study from the legacy eIRB Services system into Kuali, it is important to know the previous review type that the study received. Unfortunately, this is not always obvious from the letters the Office of IRB Administration (OIA) had sent out. Please use the below as a handy guide:

1. Not Human Subjects Research (NHSR)/Evidence Based Practice (EBP)/Quality Improvement (QI)/Quality Assurance (QA)

Studies with this review type may have a “QI” after their project number on the letter generated by OIA in the legacy system and will look similar to the example below:

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Date: August 8, 2020
To: Dr. [Redacted]
Re: Project # [Redacted] QI

Dear Dr. [Redacted],

Your project has been reviewed by the Director of the UCSD HRPP, IRB Chair, or IRB Chair’s designee and is certified as not qualifying as human subjects research according to the Code of Federal Regulations, Title 45, part 46 and UCSD Standard Operating Policies and Procedures; and therefore, does not require IRB review.
2. Exempt

OIA may determine that a study qualifies for “Exempt” status when the study poses no more than minimal risk to subjects and meets one of the 6 categories of exemption. Studies with this review type will have an “XX” after their project number on the letter generated by OIA in the legacy system and will have a header similar to the example below:

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Date: May 12, 2011
To: [Redacted]
Re: Project # XX
Exempt Research Application | Exempt Category 4

Dear Dr. [Redacted]

Your project was reviewed by an IRB Chair, IRB Chair designate, or the Director of the Human Research Protections Program and certified as exempt from IRB approval under 45 CFR 46.101(b), category 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3. Expedited

OIA may determine that a study qualifies for “Expeditied” status when the study poses no more than minimal risk to subjects and meets one of the 9 categories for expedited review. Studies with this review type may have a “CX,” “RX,” “SX,” “X,” “XF,” or “XL” after their project number on the letter generated by OIA in the legacy system and will have the following language included in the approval letter as shown in the example below. Please note, the listed expedited category may be different as this is just an example.

“This study was reviewed through the expedited review procedure as authorized by 45 CFR 46.110 and falls under the following research category: (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).”

4. Full Board

If a study is human subjects research and does not qualify for review at the Exempt or Expedited level, it will be reviewed by the full board. These studies will not have any of the above notations at
the end of their project numbers and will not contain the Expedited language shown in the above example.

5. **External Reliance**

When OIA cedes its review to an outside IRB (E.g. SDSU, WCG/WIRB, Advarra, etc.) one of the following letter combinations will be included at the end of the project number “AD,” “AY,” “BY,” “CB,” “GB,” “NY,” “QB,” “SY,” “UY,” or “WB” and the letter generated by OIA will look similar to the below.

![University of California, San Diego Human Research Protections Program]

Date: November 23, 2020

To: Dr. [Redacted]

Re: Project # [Redacted] AD

Dear Dr. [Redacted]

This document provides a Clearance Notification for Advarra to assume IRB oversight of Project AD. You may now submit the study to Advarra with this Clearance document attached to the submission.

6. **Humanitarian Use Device (HUD)**

While not research, the use of a HUD to treat a patient is required to be reviewed by an IRB. When OIA reviews and approves of such use, the project number will have an “H” at the end. In addition, the approval letter will contain the following language:

“The Humanitarian Device Exemption request was reviewed in compliance with the provisions of 21 CFR 814.124(a) by the Institutional Review board.”

7. **Stem Cell Research Oversight (SCRO) Committee Review**

OIA is also responsible for administering the SCRO Committee, sometimes also referred to as ESCRO. These reviews are often conducted in parallel with IRB review as the studies often also involve human subjects research. However, sometimes research that is subject to SCRO oversight does not involve human subjects and so IRB review is not required.
The easiest way to tell whether a particular study was reviewed by SCRO and the IRB or just SCRO is to look at the signatures at the end of the letter. Studies reviewed by the SCRO and IRB will have both the signature of our SCRO chair (Dr. Mark Lawson) as well as the former Interim OIA Director (Kip Kantelo). If the study involved SCRO review without IRB review, the letter will only have the signature of the SCRO chair.