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| <b>UC San Diego</b><br><b>INSTITUTIONAL REVIEW BOARD ADMINISTRATION</b> | <b>OIA-080 SOP: IRB Formation</b> |            |          |              |        |
|   | NUMBER                            | DATE       | AUTHOR   | APPROVED BY  | PAGE   |
|   | OIA-080                           | 06/21/2024 | K. Pratt | G. Firestein | 1 of 1 |

## 1 PURPOSE

- 1.1 This procedure establishes the process to form a new IRB.
- 1.2 The process begins when the institutional official, Office of IRB Administration (OIA) director, or designee determines the need for a new IRB.
- 1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated, and all members have completed training.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Updated procedures to align with Office for Human Research Protections (OHRP) requirements for updating IRB Organization (IORG) and FWA.

## 3 REQUIREMENTS

- 3.1 IRB rosters are maintained using the *OIA-601 DATABASE: IRB Roster*, or equivalent.

## 4 RESPONSIBILITIES

- 4.1 OIA staff members carry out these procedures.
- 4.2 The institutional official or designee appoints IRB members, alternate members, IRB chairs, and if applicable, other officers (e.g., vice chairs).

## 5 PROCEDURE

- 5.1 Determine from the institutional official, OIA director, or designee whether the new IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this in the IRB identifier field of the *OIA-601 DATABASE: IRB Roster*, or equivalent.
  - 5.1.1 Institutional official or designee selects:
    - 5.1.1.1 At least five individuals to serve as IRB members.
    - 5.1.1.2 Additional individuals to serve as alternate IRB members, if needed.
    - 5.1.1.3 At least one of the individuals to be the IRB chair.
  - 5.1.2 Follow *OIA-082 SOP: IRB Membership Addition* for each IRB member.
  - 5.1.3 Use *OIA-304 WORKSHEET: IRB Composition*, or equivalent, and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
  - 5.1.4 Update the IORG with the new IRB within 90 days.<sup>1</sup>
    - 5.1.4.1 File the updated IORG registration.<sup>2</sup>
  - 5.1.5 If the new IRB will meet on a regular basis, OIA staff will work with the IRB members to determine the meeting schedule. Once an agreed upon schedule is determined, update the electronic system and OIA website to reflect the new IRB's schedule, and disseminate via an appropriate means of communication to the research community.
  - 5.1.6 Notify the institutional official or designee and OIA director when the new IRB has been fully constituted and scheduled for regular meetings, as applicable.

## 6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-082 SOP: IRB Membership Addition*
- 6.3 *OIA-304 WORKSHEET: IRB Composition*
- 6.4 *OIA-601 DATABASE: IRB Roster*

## 7 REFERENCES

- 7.1 [45 CFR 46.107](#), [45 CFR 46.108\(a\)\(2\)](#), [45 CFR 46.115\(a\)\(5\)](#)
- 7.2 [21 CFR 56.107](#), [21 CFR 56.115\(a\)\(5\)](#)
- 7.3 [UC San Diego PPM 100-5](#)

<sup>1</sup> See <http://www.hhs.gov/ohrp/assurances/>.

<sup>2</sup> File via electronic submission system at Web site: <http://ohrp.cit.nih.gov/efile/>.