

## Annual Report for the Institutional Review Board – FY 2019

This report describes the activities of the Institutional Review Board (IRB) beginning June 1, 2018 and ending May 31, 2019 (FY 2019).

As shown in Table 1, 80 new protocols were submitted to the IRB in FY 2019 (versus 104 in FY 2018 and 107 during FY 2017), and 1 protocol originally submitted in FY 2018 was submitted with revisions for approval in FY 2019. Of these 81 protocols, 2 protocols received full board review (2.47%), 26 protocols were classified as expedited (32.10%), and 49 were classified as exempt (60.49%). Two protocols (2.47%), were reviewed and returned to the investigator with comments and suggested edits, but were later withdrawn. Two protocols were received and deemed “not human subjects research” (2.47%).

**Table 1. IRB Protocol Classification in FY 2019**

<b>Classification</b>	<b>Summer 2018</b>	<b>Fall 2018</b>	<b>Spring 2019</b>	<b>Total</b>
Full Board	1	0	1	2
Expedited	3	17	6	26
Exempt	8	25	16	49
Withdrawn	0	1	1	2
Not Human Subjects Research	0	1	1	2
<b>Total</b>	<b>12</b>	<b>44</b>	<b>25</b>	<b>81</b>

As shown in Table 2, IRB protocols were submitted by 18 departments, programs, and/or offices in FY 2019. Departments that submitted protocols most frequently included Psychology, Health and Human Physiological Sciences, and Political Science.

**Table 2. IRB Protocols Submitted by Department / Program / Office in FY 2019**

<b>Department / Program / Office</b>	<b>Summer 2018</b>	<b>Fall 2018</b>	<b>Spring 2019</b>	<b>Total</b>
American Studies	0	1	0	1
Anthropology	1	0	0	1
Computer Science	0	1	0	1
Dance	1	1	1	3
Economics	0	0	3	3
Education Studies	0	1	2	3
Environmental Studies and Sciences	0	1	1	2
Gender Studies	0	5	0	5
Health and Human Phys. Sciences	3	8	4	15
History	0	0	1	1
Institutional Research	0	1	0	1
Management and Business	0	1	1	2
MALS	0	1	0	1
Political Science	0	7	2	9
Psychology	7	7	13	27
Scribner Library/Tang Museum	0	2	0	2
Social Work	0	0	1	1
Sociology	0	1	2	3
<b>Total</b>	<b>12</b>	<b>38</b>	<b>31</b>	<b>81</b>

As shown in Table 3, of the 81 protocols reviewed in FY 2019, 35 were submitted by student investigators with a faculty advisor, compared with 50 protocols submitted by student investigators in FY 2018.

**Table 3. IRB Protocols Submitted by Student Investigator with Faculty Advisors in FY 2019**

<b>Department / Program / Office</b>	<b>Summer 2018</b>	<b>Fall 2018</b>	<b>Spring 2019</b>	<b>Total</b>
American Studies	0	1	0	<b>1</b>
Dance	0	1	0	<b>1</b>
Economics	0	0	2	<b>2</b>
Education Studies	0	0	1	<b>1</b>
Gender Studies	0	5	0	<b>5</b>
Health and Human Phys. Sciences	0	5	3	<b>8</b>
MALS	0	1	0	<b>1</b>
Political Science	0	2	1	<b>3</b>
Psychology	3	4	3	<b>10</b>
Sociology	0	1	2	<b>3</b>
<b>Total</b>	<b>3</b>	<b>20</b>	<b>12</b>	<b>35</b>

As shown in Table 4, the IRB reviewed and approved 47 amendment requests to previously approved protocols in FY 2019, compared to 62 amendment requests in FY 2018.

**Table 4. Number of Amendment Requests Approved in FY 2019**

	<b>Summer 2018</b>	<b>Fall 2018</b>	<b>Spring 2019</b>	<b>Total</b>
IRB Amendment Requests	10	21	16	<b>47</b>

Continuing Review Forms were sent to investigators for all active expedited and full-board protocols prior to their expiration date. 36 protocols received approval in FY 2019 to remain active, while 30 protocols received approval to be closed.

No adverse events were reported to the IRB in FY 2019.

In January, the IRB informed the Skidmore community regarding revisions to the Common Rule (the regulations governing the use of human subjects in research) that went into effect January 21, 2019. These revisions are commonly referred to as the "revised Common Rule," the "Final Rule," or the "2018 Common Rule." The revised Common Rule only applies to new studies approved on or after January 21, 2019; amendments to and continuing review of studies approved before January 21, 2019 are reviewed in accordance with the previous Common Rule. The most significant changes that affect research institutions, Institutional Review Boards (IRBs), and investigators are provided below.

1. Definitions: Although the criteria for what constitutes human subjects research has not changed, the actual text has. The definition of "human subject" has been changed to include "identifiable biospecimens" as well as how data and/or biospecimens have been collected or will be used.


2. The definition of “research” has also been expanded to list activities that are specifically deemed not to be research (e.g., oral history, journalism, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions)
3. Informed Consent: The revised regulations include new requirements for the content, presentation and organization of information so potential participants have all the information they need to make an informed decision. Consent forms will need to include key information at the beginning of the form and be presented at the outset of the consent discussion with participants to explain the research in an easy-to-understand and clear manner. Consent forms will also need to include information regarding the potential for future use of de-identified data and biospecimens.
4. Limited IRB Review: The revised regulations also incorporate an alternate path of review for studies otherwise qualifying for exemption but working with identifiable information or biospecimens. An IRB member must conduct limited IRB review for these studies. The focus of the review is limited to determining that the research design includes adequate provisions to protect participant privacy and confidentiality.
5. Exempt Research: The revised regulations impact how minimal risk research is reviewed and as such, the categories of research that qualify for exemption have been expanded and revised. New categories were added and new processes created.
6. Continuing Review: For new studies approved under the revised Common Rule, continuing review will not be required for some minimal risk research, including studies where the only remaining activity is the analysis of identifiable data/biospecimens or activity to obtain follow-up clinical data.

Membership for the IRB is listed in Table 5. Sandra Goff (Economics) was on research leave during FY 2019 but continued her service on the IRB. William Tomlinson left the IRB upon his retirement on 9/28/18. Lisa Burke began her role as IRB Coordinator on 8/27/18.

**Table 5. IRB Members**

<b>June 1, 2018 – May 31, 2019</b>
Lisa Burke, IRB Coordinator (Sponsored Research)
Andrew Demaree (Counseling Center)
Sarah DiPasquale (Dance)
Denise Evert (Psychology)
Kurt Freeman (Community-at-Large Member)
Sandra Goff (Economics)
Mary Hoehn, Chair (Sponsored Research)
Andrew Lindner (Sociology)
Bill Tomlinson (Sponsored Research, <i>ex officio</i> member)

Respectfully submitted,

  
 Mary Hoehn, IRB Chair