

## Annual Report for the Institutional Review Board – FY22

This report describes the activities of the Institutional Review Board (IRB) beginning June 1, 2021 and ending May 31, 2022 (FY22).

As shown in Table 1, 71 new protocols were submitted to the IRB in FY21 (versus 61 in FY21 and 95 in FY20). Of these 71 protocols, 26 were classified as expedited (36.62%) and 35 were classified as exempt (49.29%). One protocol was classified as full board (1.41%), and 9 protocols (12.68%) were submitted but later withdrawn.

**Table 1. IRB Protocol Classification in FY22**

<b>Classification</b>	<b>Summer 2021</b>	<b>Fall 2021</b>	<b>Spring 2022</b>	<b>Total</b>
Full Board	0	0	1	<b>1</b>
Expedited	3	14	9	<b>26</b>
Exempt	7	11	17	<b>35</b>
Withdrawn	0	9	0	<b>9</b>
<b>Total</b>	<b>10</b>	<b>34</b>	<b>27</b>	<b>71</b>

As shown in Table 2, IRB protocols were submitted by 16 departments, programs, and/or offices in FY22. Departments that submitted protocols most frequently included Psychology, Health and Human Physiological Sciences, Economics, and Political Science.

**Table 2. IRB Protocols Submitted by Department / Program / Office in FY22**

<b>Department / Program / Office</b>	<b>Summer 2021</b>	<b>Fall 2021</b>	<b>Spring 2022</b>	<b>Total</b>
American Studies	0	2	0	<b>2</b>
Anthropology	0	0	1	<b>1</b>
Biology	0	0	1	<b>1</b>
Computer Science	1	1	1	<b>3</b>
Dance	1	1	0	<b>2</b>
Economics ( <i>1 withdrawn</i> )	2	2	6	<b>10</b>
Environmental Studies & Sciences ( <i>1 withdrawn</i> )	0	2	1	<b>3</b>
Health and Human Phys. Sciences ( <i>6 withdrawn</i> )	0	8	4	<b>12</b>
Health Promotion	0	0	1	<b>1</b>
Institutional Research	0	2	1	<b>3</b>
Management & Business ( <i>1 withdrawn</i> )	0	1	0	<b>1</b>
Political Science	0	4	3	<b>7</b>
Psychology	5	11	5	<b>21</b>
Scribner Library	0	0	1	<b>1</b>
Social Work	0	0	1	<b>1</b>
Sociology	1	0	1	<b>2</b>
<b>Total</b>	<b>10</b>	<b>34</b>	<b>27</b>	<b>71</b>

As shown in Table 3, of the 71 protocols reviewed in FY22, 45 involved student investigators, compared with 39 protocols involving student investigators in FY21.

**Table 3. IRB Protocols Involving Student Investigators in FY22**

Department / Program / Office	Summer 2021	Fall 2021	Spring 2022	Total
American Studies	0	1	0	1
Biology	0	0	1	1
Computer Science	0	1	0	1
Dance	0	1	0	1
Economics	0	1	5	6
Environmental Studies & Sciences ( <i>1 withdrawn</i> )	0	2	1	3
Health and Human Phys. Sciences ( <i>6 withdrawn</i> )	0	7	3	10
Political Science	0	3	3	6
Psychology	2	9	3	14
Social Work	0	0	1	1
Sociology	0	0	1	1
<b>Total</b>	<b>2</b>	<b>25</b>	<b>18</b>	<b>45</b>

As shown in Table 4, the IRB reviewed and approved 34 amendment requests to previously approved protocols in FY22, compared to 31 amendment requests in FY21.

**Table 4. Number of Amendment Requests Approved in FY22**

	Summer 2021	Fall 2021	Spring 2022	Total
IRB Amendment Requests	6	11	17	34

Continuing Review Forms were sent to investigators for 24 protocols classified as expedited and full-board that were approved prior to January 21, 2019 (those approved after January 21, 2019 do not require continuing review). 17 protocols received approval to remain active, while 7 protocols received approval to be closed.

No adverse events or protocol violations were reported to the IRB in FY22.

Membership for the IRB is listed in Table 5.

**Table 5. IRB Members**

<b>June 1, 2021 – May 31, 2022</b>
Lisa Burke, IRB Coordinator (Sponsored Research)
Sarah DiPasquale (Dance) (through 12/31/2022)
Denise Evert (Psychology)
Sandra Goff (Economics)
Mary Hoehn, Chair (Sponsored Research)
Christopher Mann (Political Science)
William Tomlinson (Community-at-Large Member)

## COVID-19 Response

On September 13, 2021, the Office of the Dean of the Faculty and the IRB sent out a joint email to the faculty stating IRB policies and procedures would take effect immediately as follows:

### **Status Level Yellow (Substantial to High County Transmission Rate)**

- Research projects involving human subjects that will be conducted on-campus and in-person should only include Skidmore faculty, staff and undergraduates. Any proposed on-campus, in-person human subjects research that includes visitors as study participants must be approved by Michael Orr, DOF/VPAA, in addition to obtaining IRB approval.
- Unvaccinated Skidmore participants and approved, unvaccinated visitor participants are required to wear a mask covering both the nose and mouth at all times and maintain social distancing when possible for on-campus, in-person research studies.
- Vaccinated Skidmore participants and approved, vaccinated visitor participants are required to wear a mask covering both the nose and mouth at all times for on-campus, in-person research studies. Additionally, vaccinated Skidmore participants and approved, vaccinated visitor participants should maintain social distancing when possible when in the presence of unvaccinated individuals or where the vaccination status of others is unknown.
- Research projects involving human subjects that will be conducted off-campus and in-person, and for which Skidmore will serve as the designated IRB, will be subject to the **Status Level Yellow** Guidelines – regardless of Skidmore’s current status level – and may require approval by Michael Orr, DOF/VPAA, in addition to obtaining IRB approval. Specifically, the following guidelines apply for off-campus, in-person human subjects research:
  - Unvaccinated study personnel and participants are required to wear a mask covering both the nose and mouth at all times and maintain social distancing when possible.
  - Vaccinated study personnel and participants are required to wear a mask covering both the nose and mouth at all times. Additionally, vaccinated study personnel and participants should maintain social distancing when possible when in the presence of unvaccinated individuals or where the vaccination status of others is unknown.

### **Status Level Green (Low to Moderate County Transmission Rate)**

- Research projects involving human subjects that will be conducted on-campus and in-person may include Skidmore faculty, staff and undergraduates, as well as those who are not affiliated with Skidmore (i.e., visitors).
- Unvaccinated Skidmore participants and unvaccinated visitor participants are required to wear a mask covering both the nose and mouth at all times and maintain social distancing when possible for on-campus, in-person research studies.

- Vaccinated Skidmore participants and vaccinated visitor participants are not required to wear a mask for on-campus, in-person research studies. However, vaccinated Skidmore participants and vaccinated visitor participants should maintain social distancing when possible when in the presence of unvaccinated individuals or where the vaccination status of others is unknown.

### **Additional Policies and Guidelines**

- If you have a currently active IRB protocol and plan to conduct in-person human subjects research, regardless of whether it is on-campus or off-campus, you must submit a protocol amendment request that includes a detailed statement outlining how your IRB protocol will adhere to or exceed the [Fall 2021 Health and Safety Guidelines](#) that have been set forth by the College (i.e., social distancing, face masks, etc.).
- Similarly, all new IRB applications proposing in-person human subjects research, regardless of whether it is on-campus or off-campus, must include a detailed statement outlining how your IRB protocol will adhere to or exceed the [Fall 2021 Health and Safety Guidelines](#) that have been set forth by the College (i.e., social distancing, face masks, etc.).
- The "Risks" section in both the IRB application and informed consent form should address the COVID-19 risks your participants may encounter by participating in your research study and how those risks will be mitigated.
- All IRB applications proposing in-person research, regardless of whether it is on-campus or off-campus, will be reviewed by the full board. Please consult the [Meeting Schedule and Submission Deadlines](#) page for further details.
- Depending on the nature of your proposed human subjects research, the IRB may require additional procedures be included (i.e., maintaining participant contact information for the purposes of contact tracing, adverse event reporting for participants who test positive for COVID-19, etc.).

In February 2022, in conjunction with the Dean of the Faculty, the IRB updated its policies for the spring 2022 semester as follows, which remained in effect until the end of the 2021-2022 academic year:

- Research projects involving human subjects that will be conducted on-campus and in-person should only include Skidmore faculty, staff and undergraduates.
- Any proposed on-campus, in-person human subjects research that includes visitors as study participants must be approved by Michael Orr, DOF/VPAA, in addition to obtaining IRB approval.
- Research projects involving human subjects that will be conducted on-campus and in-person must detail how your IRB protocol will adhere to current College health and

safety guidelines as it relates to vaccination requirements, masking, social distancing, sanitization, etc.

- Research projects involving human subjects that will be conducted off-campus and in-person, and for which Skidmore will serve as the designated IRB, must detail how your IRB protocol will adhere as closely as possible to current College health and safety guidelines as it relates to vaccination requirements, masking, social distancing, sanitization, etc., and may require approval by Michael Orr, DOF/VPAA.
- All IRB applications proposing in-person research, regardless of whether it is on-campus or off-campus, will be reviewed by the full board to ensure your study adheres to current College health and safety guidelines as it relates to vaccination requirements, masking, social distancing, sanitization, etc., and addresses the COVID-19 risks your participants may encounter by participating in your research study, including how those risks will be mitigated.
- Depending on the nature of your proposed human subjects research, the IRB may require additional procedures be included (i.e., maintaining subject logs for the purposes of contact tracing, etc.).

#### **Additional Policies and Guidelines**

- If you have a currently active IRB protocol and plan to conduct in-person human subjects research, regardless of whether it is on-campus or off-campus, you must submit a protocol amendment request that details how your IRB protocol will adhere to current College health and safety guidelines as it relates to vaccination requirements, masking, social distancing, sanitization, etc.
- The "Risks" section in both the IRB application and informed consent form must address the COVID-19 risks your participants may encounter by participating in your research study and how those risks will be mitigated.

Respectfully submitted,



Mary Hoehn, IRB Chair