Hobart and William Smith Colleges
Institutional Review Board
Written Procedures and Policies

Part A: IRB Roles and Responsibilities at Hobart and William Smith Colleges

I. The Provost holds institutional responsibility for ensuring that HWS complies with Title 45 of the *Code of Federal Regulations*, Part 46 (45 CFR 46, Public Welfare, Department of Health and Human Services, Protection of Human Subjects, available online at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101). 45 CFR 46 implements amendments to the Public Health Service Act (PL 99-158) requiring all institutions engaged in research involving human subjects to establish an Institutional Review Board to oversee the administration of those research projects.

II. The HWS Institutional Review Board is charged by the Provost with reviewing, approving, requiring modification in, or disapproving all research activities involving human subjects conducted by members of the HWS community or on the HWS campus. The IRB is guided in its structure and deliberations by the *Nuremberg Code* (1949, https://history.nih.gov/research/downloads/nuremberg.pdf); the *Belmont Report: Ethical Principles and Guidelines* for the protection of human subjects of research (1979, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/); and the policies and guidelines of the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS), including 45 CFR 46 of the Code of Federal Regulations.

a. *The IRB Board*. As required by HHS regulations (45 CFR 46.107), the HWS Institutional Review Board will have at least five members (quorum) with varying backgrounds and professional experiences to ensure a complete and adequate review of the research activities of the institution. The Board will be composed of a diversity of members including racial, gender, and cultural backgrounds. At least one member of the Board will be a scientist by training and at least one member's primary concerns will be in non-scientific areas. At least one member will not otherwise have an affiliation with HWS and represent the interests of the community. Board members will not participate in the review of a research proposal in which they may have a conflict of interest. Board members individually and the Board collectively review, deliberate, and determine the status of research proposals consistent with the policies of the OHRP and the HWS IRB. The Board is responsible for safeguarding the rights and welfare of human participants in research projects.

b. *IRB Chair:* The Chair of the IRB is selected from the Board's membership. The Chair has sound knowledge and understanding of the Federal Guidelines relating to the Protection of Human Subjects. The Chair is responsible for:

i. setting the agenda for IRB meetings in consultation with Board members;

ii. convening and conducting IRB meetings as scheduled;

iii. ensuring that submitted research is reviewed efficiently and consistent with federal regulations; and

iv. reviewing and approving applications for expedited and exempted review, continuations, and amendments consistent with federal regulation and HWS policy.

c. *IRB Coordinator:* The IRB Coordinator is normally a member of the Office of Academic and Faculty Affairs and, on behalf of the Provost, ensures compliance with the terms of the Hobart and William Smith Federalwide Assurance. The Coordinator has sound knowledge and understanding of the Federal Guidelines relating to the Protection of Human Subjects and is generally the contact person between researchers, the IRB, the Office of Academic and Faculty Affairs, and other interested parties. Additionally, the IRB Coordinator:

i. ensures that all materials needed for IRB review are appropriately logged and distributed to IRB members in a timely manner;

ii. conducts an initial screening of all submitted materials to ensure completeness and use of appropriate forms, prior to sending proposals to IRB members for their review;

iii. communicates pertinent information and IRB decisions in a timely manner to IRB members, the IRB Chair, and researchers;

iv. ensures that IRB documentation, both current and archival, is fully and accurately maintained in the Office of Academic and Faculty Affairs in accordance with HWS policy, IRB policy, and federal regulation;

v. ensures that the IRB website is accurate and that it contains the most current version of forms, policies, and procedures;

vi. communicates the IRB's role and schedule to HWS community members;

vii. maintains minutes and records of IRB deliberations;

viii. recruits members to serve on the IRB;

ix. ensures that all IRB members and researchers have completed mandatory training associated with the federal assurance process; and

x. fulfills the duties of IRB Chair when the Chair is unable to attend meetings or has a conflict of interest in reviewing a research proposal.

III. *Faculty, staff, student and external researchers:* Consistent with federal regulations (45 CFR 46) and HWS policy, faculty, staff, and students who plan to conduct a research project involving living human subjects on the HWS campus or elsewhere need approval from the IRB before beginning their project. In addition to obtaining approval from the IRB, external (non-HWS) researchers need to obtain written approval from either the Vice President of Student Affairs (if the research is on HWS students) and/or the Provost (if the research is on HWS faculty or staff).

a. For the purposes of IRB approval, research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46) and a human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 CFR 46). Note that some research projects involving human subjects are exempt from IRB review. Researchers should consult the Guide for Preparing Research Proposals, as well as the Research Exempt from Review document, on the HWS IRB webpage for additional delineation of review and exemption requirements.

b. Researchers are expected to secure IRB approval before initiating any research involving human subjects; to follow all approved protocols in conducting their research; and to protect the rights and welfare of research participants/subjects consistent with ethical principles and values of the Belmont Report, the Nuremberg Code, federal and state laws, and the policies and expectations of HWS. Specifically, researchers are expected to:

    i. complete the online Human Participant Protections Education Training Course provided either by the NIH Office of Extramural Research (https://phrp.nihtraining.com/users/login.php) or the Collaborative Institutional Training Initiative (CITI https://www.citiprogram.org);

    ii. ensure that research is proposed and conducted according to sound research design and methods; all applicable state and federal laws and regulations; and the policies of the HWS IRB.

    iii. protect the rights, welfare, anonymity, and confidentiality of research participants and specifically to safeguard vulnerable populations;

    iv. present an accurate, clear, and complete research proposal to the IRB for approval prior to initiating any research project;

    v. comply with IRB requests for revision and modifications to research protocols;

    vi. secure IRB approval prior to initiating any research project involving human subjects;

    vii. follow all approved protocols in conducting research projects;

    viii. obtain and document informed consent of participants or participants' legal guardians prior to participation in the research, unless a waiver has been approved by the IRB;

    ix. ensure that requests for continuation are submitted in a timely manner;

    x. obtain prior approval from the IRB for any modification of previously approved projects; and

    xi. report to the IRB any unanticipated problems involving risks to subjects and comply with IRB requests involving those problems.

c. External researchers, even with IRB approval from another institution, are required to notify or obtain approval from the HWS IRB for any study to be conducted on the HWS campus or focused on HWS faculty, staff, or students. Subsequent notification and approval of the Vice President of Student Affairs (for research on HWS students) and/or the Provost (for research on HWS faculty or staff) is also required.

Part B: Institutional Review Board Meeting Policies

I. *Definition of Quorum*: The HWS IRB defines a quorum as five members, the minimum number required by Federal Regulations (45 CFR 46).

a. For review of federally funded research projects, a quorum exists when at least five of members are present, including at least one member whose primary concerns are in non-scientific areas.

b. Board members may call into the meeting (teleconference) and count towards the quorum, provided that they have received all pertinent material prior to the meeting, are actively and equally able to participate in the discussion, and have notified the Chair or Coordinator prior to the meeting. Minutes should document the teleconference and that the conditions were met.

II. *Conduct of Meetings:* The IRB will conduct its meetings based on Robert's Rules of Order.

a. Meetings will be scheduled on a bi-weekly basis during the regular academic year. Meeting dates and times will be determined by the Board prior to the beginning of each semester. Special meetings of the Board, particularly over the summer but as needed, may be called at the Chair's discretion.

b. Board decisions for final approval of a research proposal are normally made through the unanimous agreement of all members present (at a meeting with quorum).

c. Members who cannot attend a meeting may submit a list of questions and concerns on a proposal for the Board to consider, however the member does not have a formal voice in the final decision of the Board at that meeting, if quorum is achieved, and does not count toward quorum.

d. For review of non-federally-funded research, the IRB may review a proposal by e-mail if in-person quorum cannot be obtained and there is an urgent reason to do so. E-mail consideration of a proposal requires that no member of the Board objects to such a procedure (i.e., wants an in-person meeting). All Board members without a conflict of interest must be included in the e-mail communication. Approval of a proposal considered by e-mail requires the unanimous consent of at least a quorum of the IRB.

e. Any time after the third request for revisions to a research proposal, the IRB Chair may decide that the IRB must make a final decision on the research proposal and call for a formal vote of the Board.

f. A recorded vote of a majority of Board members, in attendance at a regularly scheduled meeting with quorum, is required for approval. Recorded votes only reported the numbers of affirmative, negative, abstaining, and total votes and not specific names.

III. *Minutes of IRB meetings:*

a. The IRB Coordinator is responsible for preparing and maintaining adequate documentation of IRB activities, including minutes in sufficient detail to show:

i. attendance at the meetings;

ii. actions taken by the IRB including the Chair and the Coordinator;

iii. a summary of the discussion of the research proposals and any concerns of the Board regarding the proposal;

iv. the votes on these actions, when votes are taken; and

v. a written summary of the discussion of issues and their resolution.

b. Copies of the minutes are maintained in the Office of Academic and Faculty Affairs. Beginning in the Spring semester of the 2016-2017 academic year, minutes are available to the HWS community without the current IRB Chairperson's or current IRB Coordinator's approval. Minutes prior to the Spring semester of the 2016-2017 academic year require the approval of the current IRB Chairperson and the current IRB Coordinator.

Part C: IRB Review of Research Proposals

I. *Determining the appropriate review process*: The Guide for Preparing Research Proposals and the IRB Determination Tree, both on the HWS IRB webpage, provide detailed and practical advice for researchers in determining whether IRB approval is needed and the type of review and form required for submission. The HWS IRB has two processes (a full IRB review and an expedited Chair's review) for reviewing the six forms available for IRB proposals:

a. Review exceptions: For the purposes of IRB approval, research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46). Research however does not require IRB review if any of the following statements apply to it:

i. the research will not involve obtaining information about living individuals;

ii. the research primarily consists of the collection or study of publicly available existing data, documents, records, pathological specimens, or diagnostic specimens;

iii. the research primarily consists of the study of existing data collected and recorded by the researcher in such a manner that participants cannot be identified, directly or through identifiers linked to the participants; or

iv. the research primarily will be conducted within the classroom, involving normal educational practices and tests. Note if the research is to be presented to the public (e.g., at a poster session or as a publication), this classroom exception does not apply and the project would require IRB approval ***prior*** to the initiation of the research.

b. Research proposals requiring IRB review (because they do not meet the review exceptions, C.I.a., above) fall into two categories and require a full review of the IRB ***unless*** an exemption applies:

i. independent research projects warrant a Form A, *Application to Conduct Research with Human Subjects*, proposal. However, see exemption requirements in section C.I.c below. Form A approvals are effective for a maximum of one year. A request for a continuation of a previously approved Form A requires a Form A-Continuation, *Application for Continued Research with Human Subjects*, proposal and an expedited review.

ii. course-based research projects warrant a full review using Form C, *Application to Conduct Course-Based Student Research with Human Subjects*, proposal. However, see exemption requirements in section C.I.d below. Form C approvals are effective for a maximum of one year. A request for a continuation of a previously approved Form C requires a Form C-Continuation, *Application for Continued Course-Based Research with Human Subjects*, proposal and an expedited review.

c. Independent research projects may warrant an expedited review for an exemption from IRB review using Form B, *Application for Exemption from IRB Review for Research with Human Subjects*, if the research falls in one of the following exempt categories:

i. Research conducted in established or commonly accepted educational settings, that specifically involve normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

ii. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if at least one of the following criteria is met: (a) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or (b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

iii. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or (b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. The research also does not involve deceiving the subjects regarding the nature or purposes of the research.

iv. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (a) the identifiable private information or identifiable biospecimens are publicly available; (b) information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (c) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under the health care operations of 45 CFR 160 and 164; or (d) the research is conducted by, or on behalf of, a federal department or agency using government-generated or government-controlled information obtained for nonresearch activities.

v. Research and demonstration projects that are conducted or supported by a federal department or agency, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

vi. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

vii. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review.

viii. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (a) broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens were obtained in accordance with federal law; (b) documentation of informed consent or waiver of documentation of consent was obtained in accordance with relevant federal law; and (c) an IRB conducts a

limited IRB review and makes the determination that the research to be conducted is within the scope of broad consent as defined in the Common Rule.

***and* all of the following exemption criteria apply to the project:**

i. the research does not include protected categories of human subjects, specifically children and minors (see section D.V. Research on Protected Categories—Policy on HWS Students below); pregnant women; fetuses; neonates; institutionalized persons; persons with psychiatric, cognitive, or developmental disorders; or persons under the influence of alcohol or drugs; and

ii. the research is conducted anonymously or the research does not involve the collection or recording of behavior that, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and

iii. the research does not involve deception; and

iv. the research involves minimal to no risk to human subjects; and

v. the research does not require a waiver from informed consent procedures; and

vi. the research is conducted anonymously and preserves the confidentiality

d. Course-based research projects may warrant an expedited review for an exemption from IRB review using Form D, *Application for IRB Exemption for Course-Based Student Research with Human Subjects,* if all of the following exemption criteria apply to the project:

i. the human subjects are at least 18 years old or HWS students (see section D.V. Research on Protected Categories—Policy on HWS Students below); and

ii. the research does not include protected categories of human subjects, specifically children and minors; pregnant women; fetuses; neonates; institutionalized persons; persons with psychiatric, cognitive, or developmental disorders; or persons under the influence of alcohol or drugs; and

iii. the research involves minimal to no risk to human subjects and does not involve deception; and

iv. if the data collected are not public records or observations of public behavior, informed consent will be obtained from all subjects and the data and identities of participants will remain confidential; and

v. the research will not be published or disseminated outside the HWS community (meaning faculty, staff, and students) before obtaining additional approval from the IRB; and

vi. data collected in the research project will be used only by the student researcher(s) for his/her/their classroom project and will not be used in any faculty research study without expressed approved of the IRB; and

vii. all observations or data that can be linked to or identified with specific human subjects will be destroyed upon completion of the research project and the remaining data will not be used in any other faculty or student research before obtaining additional approval from the IRB; and

viii. the faculty supervisor has completed the online Human Participants Education Training Course within the last ten years of starting the project.

II. *Full IRB Reviews:* Non-exempted research on human subjects is reviewed by the entire IRB at a regularly scheduled meeting.

a. The full IRB reviews proposals submitted as a Form A, *Application to Conduct Research with Human Subjects*, and Form C, *Application to Conduct Course-Based Student Research with Human Subjects*. The Board may also review applications for exemption from review and requests for continuation at the request of the IRB Chair.

b. Research proposals for a full IRB review are submitted to the Office of Academic and Faculty Affairs for IRB consideration, and assigned an IRB proposal number.

i. Submitted proposals should answer all relevant questions on the respective form, provide copies of all documentation to be used in the study, and have signatures from all relevant personnel.

ii. The IRB Coordinator will do a preliminary review of the proposal and then submit the proposal to the Board for their individual review.

iii. Normally, proposals received at least 72 hours prior to the Board's regularly scheduled meeting will be considered at that meeting. The timing however is dependent on the schedule and agenda of the Board, the submission and registration of the proposal into the IRB system, and the review of the IRB Coordinator.

c. Research proposals for a full IRB review are reviewed, discussed, and decided by the entire Board. In order to approve research, the IRB shall determine that all of the following requirements, amongst other things, are satisfied:

i. Risks to subjects are minimized (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying

knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

iii. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

v. Informed consent will be appropriately documented or appropriated waived.

vi. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

vii. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

d. The Board may take a variety of actions upon review of a submission. Amongst the actions available to the Board are the following:

i. Approval is given when the Board has authorized the researcher to pursue the research as described. The IRB Coordinator will communicate the approval to the researcher in an approval letter, along with a copy of the signed (by the IRB Chair) and stamped cover page of the form. Approval of projects under full review is effective for one calendar year (twelve months) from the date of approval. Continuations may be requested before the expiration of the approval period.

ii. A minor request for revision is given when the Board determines that the researcher needs to make minor, descriptive, grammatical, procedural, or prescriptive changes to the research proposal in order to meet the expectations for approval. The IRB Coordinator will communicate the concerns and areas for revision to the researcher. Once the researcher has submitted a revised version of the research proposal, the IRB Chair will reconsider the proposal and may approve the proposal on behalf of the Board, request additional revisions in line with the Board's recommendations, or present the revised proposal to the Board for reconsideration.

iii. A major request for revision is given when the Board determines that the researcher needs to make significant changes to the research proposal in order to meet the criteria for approval. The IRB Coordinator will communicate the concerns and areas for revision to the researcher. Once the researcher has submitted a revised version of the research proposal, the Board will reconsider

the proposal at its next meeting. All Board actions remain available during the reconsideration.

iv. Rejection is given when the Board determines that the proposal does not meet the criteria for approval and the IRB considers the research to have extensive deficiencies. Rejection normally follows multiple rounds of revision. The IRB Coordinator will communicate the decision and concerns of the IRB to the researcher. Reconsideration of a rejection may be requested, but normally requires a substantially revised proposal.

v. No consideration is given when the Board determines that the proposal does not require IRB proposal, because it does not meet the expectations of research (see section C.I.a.) or the parameters of the Board. The IRB Coordinator will communicate the decision and reasoning to the researcher and request greater clarification on the nature of the project if necessary.

e. Continuation of IRB-Approved Research (Form A) Beyond Four Years. If more than four years have elapsed from the end date of the originally approved proposal, the IRB Chair will re-evaluate that proposal when a continuation report is submitted to ensure that the research is still consistent with both federal regulations and current IRB policy. In the event that the Chair identifies any inconsistency, the proposal will be brought to the full IRB for resolution.

III. *Expedited Reviews of Exemptions and Continuations:* Exempted research on human subject and requests for continuations are reviewed by the IRB Chair.

a. The Chair reviews proposals submitted as a Form A-Continuation, *Application for Continued Research with Human Subjects*, Form B, *Application for Exemption from IRB Review for Research with Human Subjects,* Form C-Continuation, *Application for Continued Course-Based Research with Human Subjects,* and Form D, *Application for Exemption from IRB Review for Course-Based Student Research with Human Subjects*.

b. Research proposals for an expedited review of exemption or a request for continuation are submitted to the Office of Academic and Faculty Affairs for IRB consideration and are assigned an IRB proposal number.

i. Submitted proposals should answer all relevant questions on the respective form, provide copies of all documentation to be used in the study, and have signatures from all relevant personnel.

ii. The IRB Coordinator will do a preliminary review of the proposal and then submit the proposal to the Chair for her/his review.

c. The Chair may take a variety of actions upon review of a submission. Amongst the actions are the following:

i. Approval is made when the IRB Chair determines that the proposal meets the criteria for exemption or continuation. The IRB Coordinator will communicate the approval to the researcher in an approval letter, along with a copy of the signed (by the IRB Chair) and stamped cover page of the form. Approvals for continuations are effective for one calendar year (twelve months) after the

approval is granted. Approvals for exemptions are permanent unless changes are made to the protocols of the project or unanticipated problems arise.

ii. A request for clarification is made when the IRB Chair needs additional information to make a determination about the exemption or continuation. The request may be an indication or recommendation that the exemption or continuation should be resubmitted as a Form A or C and require the full review of the Board. The IRB Coordinator will communicate the decision and request for information and revision to the researcher. Once the researcher has submitted a revised version of the research proposal, the IRB Chair will reconsider the proposal and may approve the exemption or continuation, request additional information, or refer the revised proposal to the Board for consideration.

iii. Referral to the Board is made when the IRB Chair is uncertain about the applicability of an exemption or continuation and requests a full review by the Board. The Board may decide to approve or reject the exemption or continuation. The IRB Coordinator will communicate the decision of the Board to the researcher.

IV. *Reporting Changes and Unanticipated Problems to the IRB*:

a. Researchers and faculty/staff supervisors are responsible for reporting to the IRB Coordinator any changes to the procedures of an approved IRB proposal through a memorandum explaining the need for the change and the change.

i. For minor changes, the IRB Coordinator will obtain the approval of the IRB Chair for the request and notify the researcher of the approval if given. At her/his discretion, the Chair may seek the Board's approval for the requested change.

ii. For major changes, the IRB Coordinator will seek the Board's approval of the change. The researcher should suspend the project until the Board provides its approval.

iii. All requested and approved changes are reported to the Board by the IRB Coordinator or Chair.

b. Researchers and faculty/staff supervisors are responsible for reporting to the IRB Coordinator any unanticipated problems that arise during the research process. Alternatively, the IRB Coordinator or Chair may be notified of problems from participants or others in a study.

i. The IRB Coordinator will notify the IRB Chair (or vice versa) and the Chair will determine what actions should be taken in response to the problem. Actions may include the revision, suspension, or termination of the project. The Chair may also consult with the full Board in making a decision. The Board and the researcher should be notified in a timely manner of the Chair's decision.

ii. The IRB is responsible for sharing all reports of problems involving risks to participants or others with the Provost. If necessary, the Provost will report the event to the Office of Human Research Protections of the U.S. Department of Health and Human Services.

Part D: HWS IRB Policies for Research Proposals

I. The following items are specific policies of the HWS Institutional Review Board concerning its handling of research issues and cases before it.

II. *Observation of Online Public Behavior:* Data collected using publicly available on-line sources (e.g., chat rooms) can be used in research projects and the researcher does not need to submit an application to the IRB as long as: a) there is no interaction between the researcher and the subject, and b) the subjects cannot be identified by the researcher.

III. *Active and Passive Parental Consent for Research with Minors:* In principle, the IRB will allow the use of passive parental consent for research with minors on the condition that the researcher obtain written permission to employ passive consent from the head of the relevant school or school district. (Note: the researcher is required to provide a copy of the letter to the IRB.) Researchers are advised, however, that this policy does not guarantee that passive consent is acceptable in every instance, only that the IRB is willing to consider its use on a case-by-case basis.

IV. *Oral History Research:* Research based on oral history requires submission of an application to the IRB.

V. *Research on Protected Categories—Policy on HWS Students:* HWS students under 18 can participate in research without parental consent, when the participation is inadvertent. In other words, if the purpose of the study were to examine perspectives of 17-year olds, then even HWS students would need parental consent. However, a broad study of HWS students (who are by far all 18 and older) that inadvertently captures some 17 year olds is acceptable. Additionally, non-minor individuals from other protected classes can participate if their protected status is irrelevant to the purposes of the research and the research poses no additional risks to the subjects. Any research that targets minors or other protected categories requires parental consent (for minors) and a full review (for all protected categories).

VI. *News Reporter Activities Conducted by HWS Students:* News reporter activities conducted by HWS students do not require IRB approval.

VII. *Institutional Research:* In general, the IRB does not consider institutional research subject to IRB review. In making a specific determination, the IRB will be guided by federal policy as specified in section 101(b)(1) of the 46 CFR 45, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/. Institutional research in this case is defined as "research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies and (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."

VIII. *Changes in Principal Investigator:* If a new Principal Investigator takes over a previously-approved on-going research project, she/he is not required to submit an entirely new Form A

application but rather should submit a Form A-Continuation indicating the change in personnel.

IX. *Form D, Subsequently Wishes to Publish:* Course-based research approved under a Form D exemption normally cannot be published or presented elsewhere. If a researcher does want to publish or present data collected under a Form D-exempted project, and each participant has signed a release allowing for publication*, the researcher would then be free to publish or present the data. If each participant has not signed a release, the researcher may publish only if the following three conditions are met: (1) participants were not told that the data would not be published or presented, (2) publishing or presenting the data poses no additional risk to participants, and (3) permission to publish or present the data is obtained by submission of a new Form A or B to the IRB.

*Researchers should note that a release from a participant to publish results of a project that was conducted under a Form D Exemption does not constitute a release or assignment of copyright associated with any works created by the participant during the study. Please consult the Colleges' Policy on Intellectual Property regarding license and assignment of copyright.