

**Faculty Senate Meeting**  
Tuesday, February 27, 2018  
3:30p.m. – 5:30p.m., Toepfer Room, Adelbert Hall,

3:30 p.m.	Approval of Minutes from the January 30, 2018, Faculty Senate Meeting, <i>attachment</i>	Juscelino Colares
3:35 p.m.	President and Provost's Announcements	Barbara Snyder Bud Baeslack
3:40 p.m.	Chair's Announcements	Juscelino Colares
3:45p.m.	Report from the Executive Committee	Cynthia Beall
3:50 p.m.	Proposed Revisions to the Human Research Protection Policy, <i>attachment</i>	Kenneth Ledford
4:00 p.m.	Graduate Studies Committee: Incomplete Grade Policy	Paul MacDonald Lynmarie Hamel
4:10 p.m.	Graduate Studies Committee: Proposed Guidelines to Create a University Certificate and Professional Certification	Paul MacDonald Lynmarie Hamel
4:25 p.m.	Approval of CWRU 5-Year Calendar	Carlier Myers
4:30 p.m.	Update on Provost Search	Roy Ritzmann Suzanne Rivera
4:40 p.m.	CUE Status Update	Kimberly Emmons



## Faculty Senate

**Faculty Senate Meeting**  
**Tuesday, February 27, 2018**  
**3:30 pm to 5:30 pm**  
**Adelbert Hall, Toepfer Room**

### **Members Present**

Rohan Akolkar  
Amy Backus  
Bud Baeslack  
Cynthia Beall  
Karen Beckwith  
Jaime Bouvier  
Matthias Buck  
Gary Chottiner  
Juscelino Colares  
Christopher Cullis  
Lisa Damato  
Simone Dekker  
Evelyn Duffy

Kimberly Emmons  
Steven Eppell  
Archishman (Prince) Ghosh  
Peter Harte  
Sudha Iyengar  
Kathleen Kash  
Thomas J. Kelley  
Ruth A. Keri  
Ahmad M. Khalil  
Kenneth Ledford  
Paul MacDonald  
Gerald Mahoney  
Maureen McEnergy

David Miller  
Satish Nambisan  
Susan Painter  
Andres Pinto  
Dana Prince  
Roger Quinn  
Beverly Saylor  
Peter Shulman  
Barbara Snyder  
Ali Syed  
Rebecca Weiss  
Chris Winkleman  
Jo Ann Wise

### **Members Absent**

Harihara Baskaran  
Leon Blazey  
Christine Cano  
Bo Carlsson  
Philip Cola  
Steve Feldman  
Sahil Gulati  
Steven Hauck  
Susan Hinze  
Paul Iversen

Anne Matthews  
William Merrick  
Thomas Montagnese  
Leena Palomo  
Aaron Perzanowski  
Andrew Pollis  
Renato Roperto  
R. Mohan Sankaran  
William P. Schilling  
Glenn Starkman

Usha Stiefel  
Valerie Boebel Toly  
Ibrahim Tulunoglu  
Dustin Tyler  
Joachim Voss

### **Others Present**

Jonathan Carlson  
Nicole Deming  
Stephanie Endy  
Arnold Hirshon

Carlier Meyers  
Dean Patterson  
Suzanne Rivera  
Marilyn Sanders Mobley  
Jennifer Scharf-Deering

Jeff Wolcowitz  
Victoria Wright



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### **Call to Order**

Professor Juscelino Colares, chair, Faculty Senate, called the meeting to order at 3:30 p.m.

### **Approval of Minutes**

The Senate approved the minutes from the January 30<sup>th</sup>, 2018 Faculty Senate meeting with one change. *Attachment*

### **President's Announcements**

The President reported that Prof. Colares gave a report at the February Board of Trustees on Faculty Senate activities. The Board also heard reports from the CUE and on the Student Success Initiative. The President said that she and Lou Stark, Vice President of Student Affairs, have been meeting with student groups to obtain feedback on what the university does right and what it does wrong.

The President said that closing the university between Christmas and New Years' this year was extremely popular and that they are considering implementing this on a permanent basis. She asked faculty for their reactions. There was concern expressed by faculty that they will lose staff productivity that cannot be recovered for those staff being paid with grants funds. It is also costly to cease and then restart lab operations.

The President said that the university is monitoring any potential changes in the Deferred Action on Childhood Arrivals program (DACA), but for now, nothing has changed and a deadline for a decision has not been announced. The administration will keep the university community informed.

The President reminded the Senate about the reception following the meeting.

### **Provost's Announcements**

The Provost reported that there would be a meeting tonight with the Undergraduate Student Government to discuss feedback on the CUE recommendations.

### **Chair's Announcements**

Prof. Colares encouraged all in attendance to attend the reception following the meeting. He also said that the end of the year luncheon and budget meeting is scheduled for Friday, May 4<sup>th</sup>. More details will be forthcoming from the Faculty Senate office. Today's meeting will include an update on the Provost Search from the co-chairs of the Search Committee. While the search is confidential, they will provide the Senate with details on the process.



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### **Report from the Executive Committee**

Professor Cynthia Beall, vice chair of the Senate, reported on items from the February 13<sup>th</sup> Executive Committee meeting:

1. The Committee approved the slate of chairs for the Faculty Senate standing committees for 2018-19.
2. Professor Ron Occhionero, SODM, presented a proposal for a dental assistant pre-baccalaureate certificate for high school graduates and community college students. The Executive Committee explained that many administrative and faculty matters remained to be attended to before the it could fully consider the proposal. Prof. Occhionero was directed to Don Feke for guidance.
3. Professor Joachim Voss, chair of the Minority Affairs Committee, reported on that committee's work. This included analyzing the results of the 2016 survey of minority faculty (n=50 – 60), discussing ways in which the OIDEO office can provide career and professional development for minority faculty and discussing the idea of minority faculty cluster hiring.
4. Professor Jo Ann Wise, SOM representative to the Executive Committee, reported that faculty are concerned about the school's finances due to a large amount of debt that is expected to increase due to the new Health Education Campus; because some departments such as Anatomy and Biochemistry do not have chairs and there are no ongoing searches for new chairs because the number of tenured and tenure-track faculty is declining in a number of departments; and because there is widespread use of salary supplements in lieu of raises. The salary supplements for specific roles are taken away when the faculty member loses that role. In contrast, faculty base salaries are rarely taken away.
5. Professor David Miller, MSASS representative to the Executive Committee, gave a report from MSASS. The school has completed its strategic plan and is poised to begin a new planning process to align with a new Provost's vision. The online MSSA program is doing well and accounts for nearly 50% of the school's enrollment and 50% of tuition revenue. There are a number of faculty retirements and/or reductions in status (e.g., from full- to halftime) on the horizon. This will create workload issues. The school will be looking to recruit new faculty.
6. Vice President of Research Suzanne Rivera presented a proposed faculty conflict of commitment policy to be incorporated into the university's conflict of interest policy. The policy she presented had been reviewed by the Faculty Senate Research and Personnel Committees. The Research Committee requested modifying the proposed requirement that faculty request and receive prior approval from their chair or dean before engaging in non-



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university activities. The Research Committee requested faculty be required to simply disclose. The Personnel Committee requested that the requirement be eliminated completely.

Vice President Rivera responded to the committees by saying that the Faculty Handbook already includes a requirement for prior approval. After further discussion, the Executive Committee voted to forward the policy to the Senate By-Laws Committee for discussion of these issues with Vice President Rivera and Professor Christine Cano, chair of the Personnel Committee.

### **Proposed Revisions to the Human Research Protection Policy**

Professor Kenneth Ledford, chair of the Senate By-laws Committee, reported that the By-Laws Committee approved proposed revisions to the Human Research Protection Policy contained within the Faculty Handbook. Prof. Ledford deferred to Suzanne Rivera, Vice President for Research, to present the proposed revisions. Vice President Rivera explained that in the past, CWRU's IRB reviewed social/behavioral/educational studies but not biomedically-oriented research. This has changed and the university's IRB can now review biomedically-oriented research not conducted in a hospital setting or that involves patients, employees, data, and/or equipment at one of three affiliated hospitals. The Faculty Handbook is being revised to reflect this change. The Senate voted to approve the proposed revisions. *Attachment*

### **Graduate Studies Committee: Incomplete Grade Policy**

Professor Paul MacDonald, chair of the Faculty Senate Committee on Graduate Studies, presented an update to the Incomplete Grade Policy for graduate students. Students will now be required to make up the incomplete work by the 11<sup>th</sup> week of the semester following the one in which the incomplete was received, rather than by the last day of the semester which is current practice. The revised policy also includes language on when and how an incomplete grade is to be changed to an evaluative grade (including a failing grade if the work is not completed on time). The Senate voted to approve the revised policy. *Attachment*

### **Graduate Studies Committee: Proposed Guidelines to Create a University Certificate and Professional Certification**

Professor Paul MacDonald, chair of the Faculty Senate Committee on Graduate Studies, presented the Proposed Guidelines to Create a University Certificate and Professional Certification. Currently there is no officially recognized university definition of what constitutes a certificate program. Certificates vary widely across academic units and there is no university-level process for defining or approving criteria and standards. Certificate completion is generally not noted on the student's transcript. The guidelines define the different types of university certificates that may be offered, and establish the minimum requirements for the certificate to be officially recognized by the university and noted on the student's transcript.



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The guidelines don't eliminate existing certificates or prevent the development of new certificates that don't meet the university criteria.

Proposals for post-baccalaureate certificates are reviewed by the Graduate Studies Committee of the Faculty Senate, and/or the Faculty Senate Committee on Undergraduate Education, as determined by the Faculty Senate Executive Committee, following review and approval through the offering academic unit. Post Baccalaureate certificates are to be approved by the Faculty Senate before implementation. The Faculty Senate voted to approve the proposed Guidelines. *Attachment*

### **Approval of CWRU 5-Year Calendar**

Carlier Myers, Associate Registrar, presented the University's 2018-2023 Academic Calendar and the Senate approved the calendar. *Attachment*

### **Update on Provost Search**

Professor Roy Ritzmann and Suzanne Rivera, Vice President for Research, co-chairs of the Provost Search Committee, provided the Senate with an update on the Provost search. They described the process by which the position description had been developed. Feedback received via campus forums open to the entire community, and meetings with deans and former Faculty Senate chairs was used to create the position description. The Search Committee met numerous times to review candidates provided by a search firm. The list was narrowed down and several candidates came to Cleveland for interviews off campus. A list of 3 candidates was identified and presented to the President. The President subsequently met with the Search Committee to discuss the candidates and all three were brought to campus to meet with members of the Case community. The final candidate will be selected by the President and presented to the Board of Trustees. Prof. Ritzmann expressed his satisfaction with the process and with members of the Committee. The President thanked the co-chairs for their excellent work.

### **CUE Update**

Professor Kimberly Emmons, chair of the Commission on the Undergraduate Experience (CUE) gave an update on feedback received from the undergraduate program faculty schools as well as other groups on the CUE recommendations:

1. **University General Education Requirements** – there was general support for a unified UGER, however, the feedback was mixed with respect to content of the GERS. FSCUE and the CUE are continuing their discussions of this item.



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2. **Explore Curriculum-** Feedback was mixed with interest in providing hands-on experiences for students but concerns about over-programming and some confusion about specifics and implementation. FSCUE and the CUE are continuing their discussions of this item.

3. **Celebrating CWRU Traditions-** The feedback was positive about the CWRU Day and the Capstone Celebration Day, however, there was some concern about losing contact hours in academic courses. FSCUE and the CUE are continuing their discussions of this item.

4. **CWRU Advising Teams-** Feedback was fairly negative with concerns about perceived costs, interest in increasing tenure-track faculty, and the need for resources to improve faculty advising and mentoring. A Student Success Planning Group has been formed with administrative and faculty participation to develop a proposal designed to increase student success/satisfaction and FSCUE and the CUE are discussing this item also.

5. **Curricular Review –** Feedback was mixed with support for more flexibility but a concern about how to create more curricular space. Resources to support this effort was of concern also. There was some confusion over the relationship between Intellectual Diversity requirements and the ability to obtain an unrelated minor. FSCUE and the CUE are continuing their discussions of this item.

6. **Foster a Thriving, Diverse and Inclusive Community-** There was universal support for this item, with some concern over whether the major recommendations from the CUE will have the intended result. The Office of Student Affairs is about to begin student focus groups to inform this recommendation.

Prof. Emmons reported that the next steps for the CUE is to develop a final report for the Provost and the Senate by the end of the semester. As stated above, the CUE is also working with FSCUE to develop more concrete plans. Prof. Colares said that there are only two remaining Faculty Senate meetings during the academic year- March 28th and April 23<sup>rd</sup>.

Prof. Colares reminded all senators to complete Diversity 360 training.

The meeting was adjourned at 4:45p.m.

## **B. University Policy on Human Research Protection**

### **Purpose**

The promotion of scholarship and the discovery of new knowledge through research are among the major functions of Case Western Reserve University (CWRU) as an institution of higher learning. If this research is to be meaningful and beneficial to humanity, involvement of human subjects as study participants is necessary. It is imperative that investigators in all disciplines protect the rights and welfare of human subjects.

University policy and federal regulations mandate compliance with all applicable requirements. Moreover, faculty investigators also have a moral obligation to humankind. The interests of society and the rights of individual subjects must be protected as investigators carry out the mandate to advance knowledge. Research may entail risks to human subjects. Therefore, investigators are obligated to weigh those risks in light of potential benefits to the subject and/or to society.

### **Mission**

The mission of CWRU's Human Research Protection Program (HRPP) is to protect the rights and welfare of human research subjects by ensuring that the oversight of human research is appropriate and in accordance with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.<sup>2</sup>

### **Scope**

The CWRU HRPP covers all human research conducted by any student, employee, trainee, or faculty member (whether paid or unpaid) of CWRU ("CWRU investigator"). It includes any human research conducted at CWRU or cooperating institutions pursuant to a grant, contract, cooperative agreement, or other award to CWRU. Cooperating institutions include: University Hospitals Cleveland Medical Center, the MetroHealth System (MHS), the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) and the Cleveland Clinic (CC). Reliance agreements in place allow CWRU to defer to the IRBs at these institutions for protocol review. Hereafter, these institutions shall be referred to as "member institutions" under the CWRU HRPP.

### **Definitions**

**Research** is defined in 45 CFR 46 as "a systematic investigation designed to develop or contribute to generalizable knowledge." Therefore, any systematic investigation designed to generate results for the purpose of publication (e.g., dissertation, thesis, journal, book, or technical report) or public presentation (e.g. speech, poster, panel, and symposium) is considered to be research.

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<sup>2</sup> Belmont Report (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved February 24, 2015, from [hhs.gov/ohrp/humansubjects/guidance/belmont.html](https://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)



**Human subject** is defined in 45 CFR 46 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.”

- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information an individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

**Minimal Risk** is defined in 45 CFR 46.102(f) as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

**Responsible or Principal Investigator** is the person responsible for the conduct of a human research study at one or more sites, whether on- or off-campus. If the human research study is conducted by a team of individuals, the responsible/principal investigator is the responsible leader of the team. The responsible/principal investigator is accountable for ensuring that the team complies with all rules and regulations and engages with human subjects properly and ethically.

An **Institutional Review Board (IRB)** is a specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects in biomedical or behavioral research [45§46.102(g), .107,.108,.109].

## **1. Conditions under which Investigations Involving Human Subjects may be pursued under the CWRU HRPP**

### **a. Ethical Principles and Regulatory Mandates**

Human research conducted under the auspices of the CWRU HRPP must be carried out in an ethical manner and in accordance with the principles promulgated by The Belmont Report: respect for persons, beneficence, and justice. In addition, investigators must comply with all applicable federal, state and local requirements related to the protection of human subjects, including Department of Health and Human Services (DHHS) regulations (i.e., 45 CFR 46) and all relevant requirements of other regulatory and funding agencies. CWRU maintains a Federalwide Assurance (FWA) with DHHS. Research must not begin until investigators have

received review and approval or verification by the CWRU IRB or another authorized IRB. CWRU applies its ethical standards to all human research regardless of funding.

All human research, except as explicitly exempted in 45 CFR 46.101(b), must undergo review by an appropriate designated IRB(s). Activities that do not meet the definition of human research (e.g., most classroom activities, quality improvement activities, non-scholarly program evaluation, and certain health surveillance activities) do not require review and approval by one of the IRBs within the CWRU HRPP. When CWRU is engaged in human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency, it will apply the regulations of that agency relevant to the protection of human subjects.

**b. Informed Consent**

An investigator may involve a human subject in research only if the investigator has obtained the informed consent of the subject or the subject's legally authorized representative, unless consent is waived by an IRB per the regulatory provisions. An investigator shall seek such consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of undue influence. Unless written documentation is waived by an IRB, the investigator must provide the participant with an informed consent document written in language that is understandable to the subject or his/her representative. The investigator cannot include in the consent process, either orally or in writing, any language through which the subject or his/her representative is made to waive or appear to waive any of the subject's legal rights, or which releases the investigator, the sponsor, the institution, or its agents from liability for negligence.

The basic elements of informed consent, as described in 45 CFR 46, are as follows:

- 1) statement that study involves research, explanation of purposes of research and expected duration of subject's participation, description of procedures to be followed, and identification of any procedures which are experimental;
- 2) description of risks or discomfort to subject;
- 3) description of benefits to subject or to others;
- 4) disclosure of alternative procedures, if appropriate;
- 5) description of the extent to which confidentiality will be maintained;
- 6) for research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs;
- 7) explanation of whom to contact if questions arise about the research, the subject's rights or whom to contact if research related injury occurs; and
- 8) statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that subject may discontinue at any time.

**c. Confidentiality of Data**

Investigators are responsible for protecting the rights of research subjects by safeguarding the confidentiality of all individual data and all data that could be used to identify subjects. Should any investigator be called upon to reveal research data to an outside entity which would in any way endanger confidentiality, it is his or her obligation to refuse to divulge such information as

privileged communication between researcher and subject, unless compelled by law. The investigator should consult with the Office of Research Administration prior to releasing any such information unless compelled by law or university policy.

The University, funding agencies, and regulatory bodies have the right to audit study data in order to ensure that human subjects are being protected adequately, and that the University is in compliance with approved protocols and its FWA. Those individuals who perform audits are bound by the same rules of confidentiality as the investigator.

**d. Investigator Non-compliance**

All CWRU investigators working with human subjects have a responsibility to comply with federal regulations and university policy. Human research non-compliance is defined as conducting research involving human subjects in a manner that disregards or violates federal, state or local requirements, or policies established by the applicable IRB. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects; inadequate or non-existent procedures for informed consent; failure to follow the current approved protocol; failure to follow recommendations made by the IRB to safeguard the rights and welfare of subjects; failure to report adverse events or request permission for proposed protocol changes to the IRB; and failure to provide required ongoing progress reports.

Per the applicable regulations, IRBs have the authority to review allegations of human research non-compliance for studies they oversee. An IRB may receive allegations in several different ways, including quality assurance auditing reports, subject complaints, internal allegations, or investigator self-reporting.

The CWRU IRB is required to report serious or continuing non-compliance to federal regulatory entities and to funding agencies or other sponsors. Additionally, CWRU is required to report serious or continuing non-compliance to federal regulatory entities when the research is federally funded and when one of CWRU's affiliated hospital IRBs is the IRB of record.

**e. Faculty Advisor Responsibility for Student Research**

A faculty member advising student research projects\* involving human subjects is responsible for assuring that the rights and welfare of the subjects of student research are adequately protected. CWRU expects that advisors will take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of IRB applications. After protocol approval, the advisor should meet regularly with his/her students in order to review their work and progress. While a student serves as the primary researcher for the protocol, the faculty advisor is ultimately responsible for the protection of the student's human subjects. A faculty member's electronic "signature" on the application indicates his/her acceptance of responsibility to comply with all administrative and federal regulations.

\* Simulated research activities in a classroom setting for purposes of teaching research techniques typically is not designed to develop or contribute to generalizable knowledge and therefore is not regulated as research.

## **2. CWRU IRB Review**

All protocols, correspondence, notifications, outcomes, and responses to stipulations pertaining to a CWRU research study must be submitted and received via the CWRU IRB electronic system. When CWRU relies on a non-CWRU IRB for approval of a protocol, the CWRU investigator is required to submit to the CWRU IRB a list of the components of the research study that he/she will be responsible for, which is considered a shell protocol. Shell protocols are generally not required for member institutions. Investigators who wish to use a non-CWRU IRB to review a study protocol should contact the CWRU Research Compliance Officer for assistance with the reliance agreement process (<https://case.edu/research/faculty-staff/compliance/irb/>).

**Exempt Determination.** All research involving human subjects that is exempt from federal regulation, must be registered with the appropriate IRB. Research may be exempt from IRB review if it meets the criteria described in 45 CFR 46. Determination of exemption must be made in accordance with the policy of the applicable IRB. If a determination of exemption is made, investigators are still responsible for ethical conduct of human research in accordance with The Belmont Report.

**Expedited Review.** Expedited review is a procedure through which human research posing no more than minimal risk may be reviewed and approved without convening a meeting of the full IRB. DHHS regulations<sup>3</sup> specifically define when minimal-risk research can receive expedited review by an IRB.

**Full Review.** All research that has not received an exemption determination or an expedited review must be reviewed at a convened meeting of the IRB where a quorum of voting members is present.

**Amendments.** Changes to a study, including, but not limited to, the enrollment criteria or sample size, recruitment methods, consent form language, procedures for data collection, or study interventions require prior approval by the IRB\*. Investigators wanting to change a procedure in a study that has already been approved by an IRB must prepare a written description of the proposed change and the reason for the change. Upon review of the proposed amendment, the IRB will then reassess the balance of risks to benefits.

\*In the unusual situation where a protocol change is required to avoid an immediate apparent hazard to a subject, the investigator may make the change prior to obtaining IRB approval but must immediately inform the IRB of the occurrence.

**Adverse Events.** An adverse event is defined as any undesirable and unintended (although not necessarily unexpected) impact on the subject, as a result of a study intervention.<sup>4</sup> Investigators

must report in writing to the relevant IRB all adverse events in accordance with the IRB's policies and procedures for reporting such events.

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<sup>3</sup> (45§46.110)

<sup>4</sup> <http://www.hhs.gov/ohrp/policy/advevntguid.html>

### **3. Studies Eligible for CWRU IRB Review**

The CWRU IRB reviews social/behavioral/educational studies and biomedical research not conducted in a hospital setting. The CWRU IRB does not review biomedical research protocols that involve patients, employees, data, and/or equipment at one of the below affiliated hospitals:

- University Hospitals Cleveland Medical Center
- MetroHealth System
- The Cleveland Clinic

Per Central VA policy, the Louis Stokes Cleveland Veterans Affairs Medical Center IRB cannot be the IRB of record for CWRU research. When research conducted at the LSCVAMC is funded through CWRU, a CWRU IRB must be the IRB of record, and that approval must be supplemented by LSCVAMC IRB approval. Investigators planning research to take place at LSCVAMC that will be funded through CWRU, should consult with the CWRU Research Compliance Officer in order to determine which IRB will be the IRB of record.

Any questions about whether a research activity can be submitted to the CWRU IRB should be referred to the CWRU IRB Office (see <https://case.edu/research/faculty-staff/compliance/irb/>).

### **4. International Research**

All human research, regardless of funding, performed outside the United States must obtain appropriate institutional IRB approval according to federal regulations and the FWA. Typically, this means IRB approval from CWRU or one of its affiliate IRBs plus local approval at the study site. The university recognizes that the procedures normally followed in the foreign countries may differ from those set forth in U.S. federal regulation.

All applicable ethical standards and regulations are applied consistently to all human research, regardless of whether it is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring; quality assurance
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process (when applicable)
- Ensuring all necessary approvals are met

- Coordination and communication with local IRBs

## **5. CWRU HRPP Components**

### **Institutional Official**

CWRU's Vice President for Research is designated as the Institutional Official (IO) for the CWRU HRPP. In addition to oversight of the HRPP, the Institutional Official ensures that CWRU evaluates Conflicts of Interests in research and conducts education on the responsible conduct of research.

The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Allocate university resources within the HRPP budget.
- Appoint and remove CWRU IRB members and IRB chairs.
- Approve and rescind authorization agreements for CWRU IRBs.
- Suspend or terminate research approved by the CWRU IRB.
- Disapprove research approved by the CWRU IRB.

### **Organizational Official**

The Associate Vice President for Research is designated as the Organizational Official. The Organizational Official is responsible for oversight of, among other things, policies, procedures, and business decisions related to how research and sponsored project administration are overseen and monitored.

The Organizational Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the HRPP budget.
- Make IRB staff personnel decisions.
- Determine upon which IRBs the university will rely<sup>5</sup>
- Place limitations or conditions on an investigator's or research staff's privileges to conduct human research.
- Develop policies and procedures related to the HRPP that are binding on the university.

The Organizational Official has the responsibility to:

- Oversee the review and conduct of human research under the jurisdiction of the HRPP
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that human research will be conducted in accordance with all applicable ethical and legal requirements.
- Institute regular, effective, educational and training programs for all individuals involved with the HRPP.
- Ensure that the research review process is independent and free of undue influence, and ensure that officials of the organization cannot approve research that has not been approved by one of the IRBs designated by the organization.

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<sup>5</sup>The organizational official can make a determination about whether CWRU will enter into an inter-institutional agreement to rely on another IRB for review and approval of research.

- Implement a process to receive and act on complaints and allegations regarding the HRPP.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas and, where necessary, remove individuals from involvement in the HRPP.
- Ensure that the HRPP has sufficient resources, including IRBs appropriate for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Fulfill federally-mandated educational requirements.

### **CWRU Investigators and Study Staff**

Investigators and research staff have the responsibility to:

- Understand the definition of Human Research.
- Consult the relevant IRB when there is uncertainty about whether an activity is human research.
- Not conduct human research or allow human research to be conducted without review and approval by an IRB designated in the CWRU FWA.
- Comply with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.
- Follow HRPP requirements.
- Follow IRB policies and procedures.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Organizational Official.
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the Organizational Official.
- Report allegations or findings of non-compliance with the requirements of the HRPP to the IRB.

### **Institutional Review Boards (IRB)**

Reliance on an IRB that is not at a cooperating institution requires an Institutional Authorization Agreement for IRB review (IAA) executed by the Institutional or Organizational Official.

The CWRU IRB, as well as any IRBs relied upon by CWRU, has the authority to, for the studies they are monitoring:

- Approve, require modifications to secure approval, and disapprove human research.
- Suspend or terminate approval of human research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process.
- Determine whether an activity is human research.
- Determine whether additional protections are warranted for studies involving vulnerable subject populations.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved.

[http://www.case.edu/president/facsen/frames/handbook/conflicts\\_of\\_interest.htm](http://www.case.edu/president/facsen/frames/handbook/conflicts_of_interest.htm)

IRB members and IRB staff have the responsibility to follow HRPP policies and procedures, including disclosure of outside financial interests and recusal from review of protocols with which the member or staff may have a conflict.

### **Legal Counsel**

Legal Counsel has the responsibility to:

- Provide legal advice upon request to the Institutional Official, Organizational Official, IRB, and other individuals involved with the HRPP.
- Help resolve conflicts among applicable laws.

### **Deans/Department Chairs**

Deans and Department Chairs have the responsibility to:

- Assure scientific review and oversee the conduct of human research in their department or school.
- Forward complaints and allegations regarding the HRPP to the Organizational Official.
- Affirm that each human research study proposed to be conducted in their department or school can be done responsibly by the study team using the resources described in the proposal.

### **Office of Research Administration**

The Office of Research Administration (and similar offices with delegated authority, such as the School of Medicine Office of Grants and Contracts) has the responsibility to review contracts and funding agreements for compliance with HRPP policies and procedures.

## **6. Education and Training**

IRB members, IRB staff, and others involved in the review of human research must complete initial and continuing training on the protection of human subjects.

Investigators and research staff must complete the initial and continuing training on the protection of human subjects.

## **7. Reporting and Management of Concerns**

Questions, concerns, complaints, allegations of undue influence, allegations or findings of noncompliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Office, the IRB Chair, the Organizational Official, Office of General Counsel, Integrity Hotline, Internal Audit Department, Deans, or Department Chairs.

The relevant IRB has the responsibility to investigate allegations and findings of non-compliance related to conduct of research for studies under its jurisdiction and take corrective actions as needed. The Organizational Official has the responsibility to investigate all other reports and take corrective actions as needed. In some instances, the IRB and the Organizational Official may, for different purposes, both be required to investigate the same matter, or may collaborate or share resources as necessary.



Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Organizational Official or designee.

To make such reports, contact:

The Office of the Associate Vice President of Research  
Sears Library Building, 6th Floor.  
2083 Martin Luther King, Jr. Drive  
Cleveland, Ohio 44106-7230  
216-368-0143

### **8. Monitoring and Auditing**

In order to monitor and assure compliance, auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic not-for-cause audits.

### **9. Disciplinary Actions**

The IRB and the Institutional Official may terminate or suspend IRB approval. In addition, the IRB and/or the Institutional Official and/or Organizational Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever, in the opinion of the IRB and/or the Institutional Official and/or Organizational Official, such actions are required to maintain the integrity of the HRPP.

## **B. University Policy on Human Research Protection**

### **\*\* Purpose**

The promotion of scholarship and the discovery of new knowledge through research are among the major functions of Case Western Reserve University (CWRU) as an institution of higher learning. If this research is to be meaningful and beneficial to humanity, involvement of human subjects as study participants is necessary. It is imperative that investigators in all disciplines protect the rights and welfare of human subjects.

University policy and federal regulations mandate compliance with all applicable requirements. Moreover, faculty investigators also have a moral obligation to humankind. The interests of society and the rights of individual subjects must be protected as investigators carry out the mandate to advance knowledge. Research may entail risks to human subjects. Therefore, investigators are obligated to weigh those risks in light of potential benefits to the subject and/or to society.

### **Mission**

The mission of CWRU's Human Research Protection Program (HRPP) is to protect the rights and welfare of human research subjects by ensuring that the oversight of human research is appropriate and in accordance with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.<sup>2</sup>

### **Scope**

The CWRU HRPP covers all human research conducted by any student, employee, trainee, or faculty member (whether paid or unpaid) of CWRU ("CWRU investigator"). It includes any human research conducted at CWRU or cooperating institutions pursuant to a grant, contract, cooperative agreement, or other award to CWRU. Cooperating institutions include: University Hospitals ~~of Cleveland~~ (UHC), Medical Center, the MetroHealth System (MHS), the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) and the Cleveland Clinic ~~Foundation (CCF)~~ (CC). Reliance agreements in place allow CWRU to defer to the IRBs at these institutions for ~~local~~ protocol review. Hereafter, these institutions shall be referred to as "member institutions" under the CWRU HRPP.

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<sup>2</sup>~~Belmont Report (1979). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Retrieved February 24, 2015, from <https://ohrp.hhs.gov/ohrp/humansubjects/guidance/belmont.html>~~

### **Definitions**

**Research** is defined in 45 CFR 46 as "a systematic investigation designed to develop or contribute to generalizable knowledge." Therefore, any systematic investigation designed to generate results for the purpose of publication (e.g., dissertation, thesis, journal, book, or technical report) or public presentation (e.g. speech, poster, panel, and symposium) is considered to be research.

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<sup>2</sup> [Belmont Report \(1979\). \*The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research\*. Retrieved February 24, 2015, from \[hhs.gov/ohrp/humansubjects/guidance/belmont.html\]\(https://www.fda.gov/oc/ohrt/belmont-report\)](https://www.fda.gov/oc/ohrt/belmont-report)

**Human subject** is defined in 45 CFR 46 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.”

- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information an individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

**Minimal Risk** is defined in 45 CFR 46.102(f) as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

**Responsible or Principal Investigator** is the person responsible for the conduct of a human research study at one or more sites, whether on- or off-campus. If the human research study is conducted by a team of individuals, the responsible/principal investigator is the responsible leader of the team. The responsible/principal investigator is accountable for ensuring that the team complies with all rules and regulations and engages with human subjects properly and ethically.

An **Institutional Review Board (IRB)** is a specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects in biomedical or behavioral research [45CFR 46.102(g), .107,.108,.109].

## **1. Conditions under ~~Which~~ which Investigations Involving Human Subjects ~~May Be Pursued~~ may be pursued under the CWRU HRPP**

### **a. Ethical Principles and Regulatory Mandates**

Human research conducted under the auspices of the CWRU HRPP must be carried out in an ethical manner and in accordance with the principles promulgated by The Belmont Report: respect for persons, beneficence, and justice. In addition, investigators must comply with all applicable federal, state and local requirements related to the protection of human subjects, including Department of

Health and Human Services (DHHS) regulations (i.e., 45 CFR 46) and all relevant requirements of other regulatory and funding agencies. CWRU maintains a Federalwide Assurance (FWA) with DHHS. Research must not begin until investigators have received review and approval or verification by the CWRU IRB or another authorized IRB. CWRU applies its ethical standards to all human research regardless of funding.

~~and approval or verification of exemption by one of the Institutional Review Boards (IRBs) listed on the CWRU FWA.~~

~~CWRU applies its ethical standards to all human research regardless of funding.~~ All human research, except as explicitly exempted in 45 CFR 46.101(b), must undergo review by ~~the~~ appropriate designated IRB(s). Activities that do not meet the definition of human research (e.g., most classroom activities, quality improvement activities, non-scholarly program evaluation, and certain health surveillance activities) do not require review and approval by one of the IRBs within the CWRU HRPP. When CWRU is engaged in human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency, it will apply the regulations of that agency relevant to the protection of human subjects.

**b. Informed Consent**

An investigator may involve a human subject in research only if the investigator has obtained the informed consent of the subject or the subject's legally authorized representative, unless consent is waived by an IRB per the regulatory provisions. An investigator shall seek such consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of undue influence. Unless written documentation is waived by an IRB, the investigator must provide the participant with an informed consent document written in language that is understandable to the subject or his/her representative. The investigator cannot include in the consent process, either orally or in writing, any language through which the subject or his/her representative is made to waive or appear to waive any of the subject's legal rights, or which releases the investigator, the sponsor, the institution, or its agents from liability for negligence.

The basic elements of informed consent, as described in 45 CFR 46, are as follows:

- 1) statement that study involves research, explanation of purposes of research and expected duration of subject's participation, description of procedures to be followed, and identification of any procedures which are experimental;
- 2) description of risks or discomfort to subject;
- 3) description of benefits to subject or to others;
- 4) disclosure of alternative procedures, if appropriate;
- 5) description of the extent to which confidentiality will be maintained;
- 6) for research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs;
- 7) explanation of whom to contact if questions arise about the research, the subject's rights or whom to contact if research related injury occurs; and
- 8) statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that subject may discontinue at any time.

**c. Confidentiality of Data**

Investigators are responsible for protecting the rights of research subjects by safeguarding the confidentiality of all individual data and all data that could be used to identify subjects. Should any investigator be called upon to reveal research data to an outside entity which would in any way endanger confidentiality, it is his or her obligation to refuse to divulge such information as privileged

communication between researcher and subject, unless compelled by law. The investigator should consult with the Office of Research Administration prior to releasing any such information- unless compelled by law or university policy.

The University, funding agencies, and regulatory bodies have the right to audit study data in order to ensure that human subjects are being protected adequately, and that the University is in compliance with approved protocols and its FWA. Those individuals who perform audits are bound by the same rules of confidentiality as the investigator.

**d. Investigator Non-compliance**

All CWRU investigators working with human subjects have a responsibility to comply with federal regulations and university policy. Human research non-compliance is defined as conducting research involving human subjects in a manner that disregards or violates federal, state or local requirements, or policies established by the applicable IRB. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects; inadequate or non-existent procedures for informed consent; failure to follow the current approved ~~version of the~~ protocol; failure to follow recommendations made by the IRB to safeguard the rights and welfare of subjects; failure to report adverse events or request permission for proposed protocol changes to the IRB; and failure to provide required ongoing progress reports.

Per the applicable regulations, IRBs have the authority to review allegations of human research non-compliance for studies they oversee. An IRB may receive allegations in several different ways, including quality assurance auditing reports, subject complaints, internal allegations, or investigator self-reporting.

The CWRU IRB is required to report serious or continuing non-compliance to federal regulatory entities and to funding agencies or other sponsors. Additionally, CWRU is required to report serious or continuing non-compliance to federal regulatory entities when the research is federally funded and when one of CWRU's affiliated hospital IRBs is the IRB of record.

**e. Faculty Advisor Responsibility for Student Research**

A faculty member advising student research projects\* involving human subjects is responsible for assuring that the rights and welfare of the subjects of student research are adequately protected. CWRU expects that advisors will take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of IRB applications. After protocol approval, the advisor should meet regularly with his/her students in order to review their work and progress. While a student serves as the primary researcher for the protocol, the faculty advisor is ultimately responsible for the protection of the student's human subjects. A faculty member's electronic "signature" on the application indicates his/her acceptance of responsibility to comply with all administrative and federal regulations.

\* Simulated research activities in a classroom setting for purposes of teaching research techniques typically is not designed to develop or contribute to generalizable knowledge and therefore is not regulated as research.

**2. CWRU IRB Review**

All protocols, correspondence, notifications, outcomes, and responses to stipulations pertaining to a ~~social/behavioral/educational~~CWRU research study must be submitted and received via the CWRU IRB electronic system. When CWRU relies on a non-CWRU IRB for approval of a protocol, the CWRU investigator is required to submit to the CWRU IRB a list of the components of the research study that he/she will be responsible for, which is considered a shell protocol. Shell protocols are generally not required for member institutions. Investigators who wish to use a non-CWRU IRB to review a study protocol should contact the CWRU Research Compliance Officer for assistance with the reliance agreement process (<https://case.edu/research/faculty-staff/compliance/irb/>).

**Exempt Determination.** All research involving human subjects that is exempt from federal regulation, must be ~~must be submitted to~~registered with the appropriate IRB. Research may be exempt from IRB review if it meets the criteria described in 45 CFR 46. Determination of exemption must be made in accordance with the policy of the applicable IRB. If a determination of exemption is made, investigators are still responsible for ethical conduct of human research in accordance with The Belmont Report.

**Expedited Review.** Expedited review is a procedure through which human research posing no more than minimal risk may be reviewed and approved without convening a meeting of the full IRB. DHHS regulations<sup>3</sup> specifically define when minimal-risk research can receive expedited review by an IRB.

**Full Review.** All research that has not received an exemption determination or an expedited review must be reviewed at a convened meeting of the IRB where a quorum of voting members is present.

**Amendments.** Changes to a study, including, but not limited to, the enrollment criteria or sample size, recruitment methods, consent form language, procedures for data collection, or study interventions require prior approval by the IRB\*. Investigators wanting to change a procedure in a study that has already been approved by an IRB must prepare a written description of the proposed change and the reason for the change. Upon review of the proposed amendment, the IRB will then reassess the balance of risks to benefits.

\*In the unusual situation where a protocol change is required to avoid an immediate apparent hazard to a subject, the investigator may make the change prior to obtaining IRB approval but must immediately inform the IRB of the occurrence.

**Adverse Events.** An adverse event is defined as any undesirable and unintended (although not necessarily unexpected) impact on the subject, as a result of a study intervention.<sup>4</sup> Investigators must report in writing to the relevant IRB all adverse events in accordance with the IRB's policies and procedures for reporting such events.

#### ~~1. Conduct of Biomedical Human Research~~

~~The CWRU IRB reviews only social/behavioral/educational and other non-biomedical human research.~~

~~When CWRU investigators wish to engage in biomedical human research, including all human research subject to FDA regulations (tests of drugs, devices, and biologics, and other biomedical interventions), they must seek review and approval from the IRB at the affiliated clinical site where the~~

study will take place. The CWRU-affiliated hospital IRBs that have agreements with CWRU to review biomedical research are:

- ~~University Hospitals of Cleveland~~
- ~~MetroHealth Hospital~~

- 
- ~~The Cleveland Clinic Foundation~~
  - ~~\*The Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC)~~

Any questions about whether a research activity is considered biomedical or otherwise subject to FDA regulations should be referred to a representative from the CWRU IRB who will provide assistance.

~~\*Per Central VA policy, the Louis Stokes Cleveland Veterans Affairs Medical Center IRB cannot be~~

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<sup>3</sup> (45§46.110)

<sup>4</sup> <http://www.hhs.gov/ohrp/policy/advevntguid.html>

### **3. Studies Eligible for CWRU IRB Review**

The CWRU IRB reviews social/behavioral/educational studies and biomedical research not conducted in a hospital setting. The CWRU IRB does not review biomedical research protocols that involve patients, employees, data, and/or equipment at one of the below affiliated hospitals:

- University Hospitals Cleveland Medical Center
- MetroHealth System
- The Cleveland Clinic

Per Central VA policy, the Louis Stokes Cleveland Veterans Affairs Medical Center IRB cannot be

<sup>4</sup> <http://www.hhs.gov/ohrp/policy/advevntguid.html>



the IRB of record for CWRU research. ~~Therefore, unless the CWRU PI has a VA appointment, another CWRU hospital IRB will need to be the IRB of record for CWRU for biomedical research.~~ When research conducted at the LSCVAMC. The CWRU is funded through CWRU, a CWRU IRB must be the IRB of record, and that approval must be supplemented by LSCVAMC IRB approval. Investigators planning research to take place at LSCVAMC that will be funded through CWRU, should consult with the CWRU Research Compliance Officer facilitates this process in order to determine which IRB will be the IRB of record.

Any questions about whether a research activity can be submitted to the CWRU IRB should be referred to the CWRU IRB Office (see <https://case.edu/research/faculty-staff/compliance/irb/>).

#### **4. International Research**

All human research, regardless of funding, performed outside the United States must obtain appropriate institutional IRB approval according to federal regulations and the FWA. Typically, this means IRB approval from CWRU or one of its affiliate IRBs plus local approval at the study site. The university recognizes that the procedures normally followed in the foreign countries may differ from those set forth in U.S. federal regulation.

All applicable ethical standards and regulations are applied consistently to all human research, regardless of whether it is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring; quality assurance
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process (when applicable)
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

#### **5. CWRU HRPP Components**

##### **Institutional Official**

CWRU's Vice President for Research is designated as the Institutional Official (IO) for the CWRU HRPP. In addition to oversight of the HRPP, the Institutional Official ensures that CWRU evaluates Conflicts of Interests in research and ~~that conducts~~ education on the responsible conduct of research-is conducted.

The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Allocate university resources within the HRPP budget.
- Appoint and remove CWRU IRB members and IRB chairs.
- Approve and rescind authorization agreements for CWRU IRBs.
- Suspend or terminate research approved by the CWRU IRB.
- Disapprove research approved by the CWRU IRB.

##### **Organizational Official**

The Associate Vice President for Research is designated as the Organizational Official. The Organizational Official is responsible for oversight of, among other things, policies, procedures, and business decisions related to how research and sponsored project administration are overseen and monitored.

The Organizational Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the HRPP budget.
- Make IRB staff personnel decisions.
- Determine upon which IRBs the university will rely<sup>5</sup>.
- Place limitations or conditions on an investigator's or research staff's privileges to conduct human research.
- Develop policies and procedures related to the HRPP that are binding on the university. ~~The Organizational Official has the responsibility to:~~

The Organizational Official has the responsibility to:

- Oversee the review and conduct of human research under the jurisdiction of the HRPP
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that human research will be conducted in accordance with all applicable ethical and legal requirements.
- Institute regular, effective, educational and training programs for all individuals involved with the HRPP.
- Ensure that the research review process is independent and free of undue influence, and ensure that officials of the organization cannot approve research that has not been approved by one of the IRBs designated by the organization.

<sup>5</sup>The organizational official can make a determination about whether CWRU will enter into an inter-institutional agreement to rely on another IRB for review and approval of research.

- Implement a process to receive and act on complaints and allegations regarding the HRPP.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas and, where necessary, remove individuals from involvement in the HRPP.
- Ensure that the HRPP has sufficient resources, including IRBs appropriate for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Fulfill federally-mandated educational requirements.

**CWRU Investigators and Study Staff**

Investigators and research staff have the responsibility to:

- Understand the definition of Human Research.
- Consult the relevant IRB when there is uncertainty about whether an activity is human research.
- Not conduct human research or allow human research to be conducted without review and approval by an IRB designated in the CWRU FWA.
- Comply with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.

- Follow HRPP requirements.
- Follow IRB policies and procedures.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Organizational Official.
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the Organizational Official.
- Report allegations or findings of non-compliance with the requirements of the HRPP to the IRB.

### **Institutional Review Boards (IRB)**

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~~<sup>5</sup>The organizational official can make a determination about whether CWRU will enter into an inter-institutional agreement to relay on another IRB for review and approval of research.~~

~~The IRBs relied upon by CWRU are listed in CWRU's FWA and on the CWRU IRB website (<https://research.case.edu/Compliance/>).~~

Reliance on an IRB that is not listed in CWRU's FWA at a cooperating institution requires an Institutional Authorization Agreement for IRB review (IAA) executed by the Institutional or Organizational Official.

The CWRU IRB, as well as any IRBs relied upon by CWRU, has the authority to, for the studies they are monitoring:

- Approve, require modifications to secure approval, and disapprove human research.
- Suspend or terminate approval of human research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process.
- Determine whether an activity is human research.
- Determine whether additional protections are warranted for studies involving vulnerable subject populations.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved.

~~([http://www.case.edu/president/facsen/frames/handbook/conflicts\\_of\\_interest.htm](http://www.case.edu/president/facsen/frames/handbook/conflicts_of_interest.htm))([http://www.case.edu/president/facsen/frames/handbook/conflicts\\_of\\_interest.htm](http://www.case.edu/president/facsen/frames/handbook/conflicts_of_interest.htm))~~

IRB members and IRB staff have the responsibility to follow HRPP policies and procedures, including disclosure of outside financial interests and recusal from review of protocols with which the member or staff may have a conflict.

### **Legal Counsel**

Legal Counsel has the responsibility to:

- Provide legal advice upon request to the Institutional Official, Organizational Official, IRB, and other individuals involved with the HRPP.
- Help resolve conflicts among applicable laws.

### **Deans/Department Chairs**

Deans and Department Chairs have the responsibility to:

- Assure scientific review and oversee the conduct of human research in their department or school.
- Forward complaints and allegations regarding the HRPP to the Organizational Official.
- Affirm that each human research study proposed to be conducted in their department or school can be done responsibly by the study team using the resources described in the proposal.

### **Office of Research Administration**

The Office of Research Administration (and similar offices with delegated authority, such as the School of Medicine Office of Grants and Contracts) has the responsibility to review contracts and funding agreements for compliance with HRPP policies and procedures.

## **6. Education and Training**

IRB members, IRB staff, and others involved in the review of human research must complete initial and continuing training on the protection of human subjects.

Investigators and research staff must complete the initial and continuing training on the protection of human subjects.

### **7. Reporting and Management of Concerns**

Questions, concerns, complaints, allegations of undue influence, allegations or findings of ~~non-compliance~~noncompliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Office, the IRB Chair, the Organizational Official, Office of General Counsel, Integrity Hotline, Internal Audit Department, Deans, or Department Chairs.

The relevant IRB has the responsibility to investigate allegations and findings of non-compliance related to conduct of research for studies under its jurisdiction and take corrective actions as needed. The Organizational Official has the responsibility to investigate all other reports and take corrective actions as needed. In some instances, the IRB and the Organizational Official may, for different purposes, both be required to investigate the same matter, or may collaborate or share resources as necessary.

Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Organizational Official or designee.

To make such reports, contact:

The Office of the Associate Vice President of Research  
Sears Library Building, 6th Floor.  
2083 Martin Luther King, Jr. Drive  
Cleveland, Ohio 44106-7230  
216-368-0143

### **8. Monitoring and Auditing**

In order to monitor and assure compliance, auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic not-for-cause audits.

### **9. Disciplinary Actions**

The IRB and the Institutional Official may terminate or suspend IRB approval. In addition, the IRB and/or the Institutional Official and/or Organizational Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever, in the opinion of the IRB and/or the Institutional Official and/or Organizational Official, such actions are required to maintain the integrity of the HRPP.

# Proposed Policy

## Assignment of the incomplete grade

The Incomplete grade (I) can only be assigned for letter-graded courses and Pass/No Pass courses by and at the discretion of the instructor when:

1. There are extenuating circumstances, explained to the instructor before the assignment of the grade, which clearly justify an extension of time beyond the requirements established for and met by other students in the class, and
2. The student has been passing the course and only an evaluative component-small segment of the course, such as a term paper, final exam or project, etc. remains to be completed.

It is the student's responsibility to notify the instructor of the circumstances preventing completion of all assigned work. In the absence of notification or adequate justification, the instructor has the authority to assign the student a final grade that assumes a failing grade for the missing work.

An Incomplete grade should not be assigned when:

1. A student has been absent for much of the semester and/or has done little of the work required for a course, or
2. A student is absent from a final examination, unless the School of Graduate Studies has authorized the grade.

The amount of additional time allowed for the student to make up incomplete work should serve to accommodate the student while being fair to other students in the course. It should be proportional to the duration of a student's illness or absence and might be no more than a few days or weeks. At the extreme, it should not extend past the 11<sup>th</sup> week of class of the semester following the one in which the incomplete grade was received.

Students may not sit in the same course in a later semester to complete the work required for the original course.

In certain cases, (such as students on probation or many incompletes in the same semester) the School of Graduate Studies may establish an earlier date for completion of courses with incomplete grades.

In exceptional circumstances a student may petition for an extension of the incomplete deadline of no more than one additional semester. The petition should be submitted by the original deadline date, and must contain the reasons for the extension, a proposed new completion date and a letter from the faculty supporting the extension.

## Changing an Incomplete Grade

When the student has completed the required work, the instructor shall enter in the Student Information System a final evaluative grade to replace the Incomplete. When a student fails to submit the work required for removing the Incomplete by the date established, the instructor shall enter a final grade that assumes a failing performance for the missing work. In the absence of the assignment of a grade by the instructor, the Registrar will convert the I to F when the deadline for making up Incomplete grades from a previous semester has passed.

# **Proposed Guidelines to Create a University Certificate and Professional Certification**

## **Background**

Case Western Reserve University has official governance processes for academic degree programs. These formal processes, which define and detail objective criteria and standards for awarding degrees, ensure that CWRU's degree programs maintain high quality and are consistent with the university's mission and strategic goals.

CWRU currently does not have an established university-level process for defining and approving criteria and standards for awarding certificates. Since there is no officially recognized university definition of what constitutes a certificate program, over the years, departments and other units of the university have established a variety of certificate programs on their own. These programs range from a single-day workshop to completion of 9-12 credit hours; some require a minimum gpa for completion and others merely require attendance at a one-day class. In these cases, the offering units individually verify completion of program requirements. Consequently, participation in or completion of certificate programs are typically not recognized on the official university transcript. If the courses that make up the certificate are regular courses that appear in the General Bulletin, the courses appear on a student's official transcript, but in most cases there is no notation on the transcript that the student is enrolled in a certificate program or that they have completed and been awarded a certificate. In some instances, the transcript will notate that the student is in a certificate program, but when they complete the program (or leave the program before completion), the transcript permanently shows that the student has been "discontinued" from the program.

There is now a growing desire to notate both participation in and completion of certificate programs on the university transcript. If this university-level recognition is to occur, CWRU must establish a formal process for approving certificate programs as well as defining and approving criteria and standards for such programs. This document intends to define the different types of certificates that may be offered at CWRU and establishes the minimum requirements for each type of certificate to be officially recognized by CWRU.

Please note, academic units can continue offering established certificate programs or develop new programs that do not meet University Certificate criteria, however, these will not be recognized on official university transcripts and the academic unit will continue to be responsible for conferring and validating its credential.

## **Definitions and Standards**

Case Western Reserve University awards University Certificates as a credential for completing a set of courses (possibly in combination with other learning experiences)

that focus on a specific topic or theme. Courses taken as part of a Certificate program are to be regular courses that appear in the General Bulletin. Certificates are recorded at the university level in the Student Information System and will appear as awarded on the student's official university transcript upon final confirmation from the units that certify degree requirements (i.e., Undergraduate Studies, Graduate Studies, school registrars).

The scope of Certificate programs is generally narrower than that expected for full degrees, and thus can normally be completed in a shorter period of time. Certificate programs may be embedded within degree programs and offered as an option for degree-seeking students, or can be stand-alone programs to which students apply and are granted admission. Courses taken as part of a certificate program may be double counted for degree programs.

#### Graduate Certificate

1. A graduate certificate program contains courses taught at the graduate or professional level.
2. The program must include a minimum of 15 credit hours.
3. The student must earn a minimum GPA of 3.00 in order for the graduate certificate to be awarded.
4. A stand-alone graduate certificate may be designated as Title IV eligible if students will be eligible for federal financial aid. Additional approval through the Provost's Office is required.
5. Proposals for graduate certificates are reviewed by the Graduate Studies Committee of the Faculty Senate, following review and approval through the offering academic unit. Graduate certificates are to be approved by the Faculty Senate before implementation. The objectives, admission requirements and learning outcomes for the certificate program must be articulated and will be considered during the review process.
6. Review by the Chancellor's Committee on Graduate Study (State of Ohio) will be required if the certificate requires 21 or more credit hours.
7. Certificates must be reported to (and if financial aid eligible must also be reviewed by) the Higher Learning Commission.
8. The certificate program may be subject to Gainful Employment reporting requirements to the federal government.
9. A description of the certificate program, including requirements for successful completion, must appear in the General Bulletin.

#### Post-Baccalaureate Certificate

1. A post-baccalaureate certificate program contains courses taught at the undergraduate and/or graduate/professional level.
2. The program must include a minimum of 15 credit hours.
3. The student must earn a minimum GPA of 3.00 in order for the post-baccalaureate certificate to be awarded.



4. A stand-alone post-baccalaureate certificate may be designated as Title IV eligible if students will be eligible for federal financial aid. Additional approval through the Provost's Office is required.
5. Proposals for post-baccalaureate certificates are reviewed by the Graduate Studies Committee of the Faculty Senate, and/or the Faculty Senate Committee on Undergraduate Education, as determined by the Faculty Senate Executive Committee, following review and approval through the offering academic unit. Post Baccalaureate certificates are to be approved by the Faculty Senate before implementation. The objectives, admissions requirements and learning outcomes for the certificate program must be articulated and will be considered during the review process.
6. Review by the Chancellor's Committee on Graduate Study (State of Ohio) will be required if the certificate requires 21 or more credit hours.
7. Certificates must be reported to (and if financial aid eligible must also be reviewed by) the Higher Learning Commission.
8. The certificate program may be subject to Gainful Employment reporting requirements to the federal government.
9. A description of the post-baccalaureate certificate program, including requirements for successful completion, must appear in the General Bulletin.

#### Professional Certification

1. Professional certification programs are intended for students who need to meet requirements and/or eligibility for licensure, exams, or board approval for certification in a particular professional area or skill.
2. A professional certification program is an approved sequence of courses that leads to a certification of completion in a specialty recognized by the school's, or discipline's, accrediting body or licensing agency.
3. The professional certification must meet the criteria set forth by the school's, or discipline's, accrediting body.
4. A stand-alone professional certification may be designated as Title IV eligible if students will be eligible for federal financial aid. Additional approval through the Provost's Office is required.
5. Proposals for professional certification are reviewed through the standard curriculum review process through the offering academic unit. Professional certifications are to be approved by the Faculty Senate before implementation. The objectives, admissions requirements and learning outcomes for the certification program must be articulated and will be considered during the review process.
6. Review by the Chancellor's Committee on Graduate Study (State of Ohio) will be required if the certification requires 21 or more credit hours.
7. The certification program may be subject to Gainful Employment reporting requirements to the federal government.
8. A description of the professional certification program, including any specific requirements for successful completion, must appear in the General Bulletin.

## **Additional Information**

### **University Undergraduate Certificate**

At this time there are no plans to offer university undergraduate certificates. Instead, “minors” play an analogous role, and these are notated on the transcripts of undergraduate students who complete them.

### **Certificates of Completion**

Various units of the university offer courses and other learning experiences aimed at continuing education or professional development. Such programs generally include courses that do not carry CWRU academic credit and which do not appear in the General Bulletin. These programs are not tracked at the university level, and are not eligible to be recorded on official transcripts. If regular credit-bearing courses are included as part of such programs, these courses will appear on an academic transcript but the transcript will not make reference to the continuing education or professional development program.

The academic or administrative units offering these not-for-credit programs may wish to issue certificates of completion to students who satisfy program requirements. In these cases, the offering units may issue such certificates, but these are not considered official university documents, and no records of the student’s participation in the program are entered into the Student Information System.

# Guidelines to Create a University Certificate

## Current Status of Certificate Programs at CWRU:

- no officially recognized university definition of what constitutes a certificate program
- no established university-level process for defining/approving criteria and standards for certificates
- current certificates vary widely across university – credits, time, GPA, Bulletin vs. non-Bulletin courses
- completion is verified by individual departments
- typically not recognized on the transcript, but when it is...

Student ID:  
SSN:  
Student Name:



Case Western Reserve University  
Cumulative Grade Report

Academic Program History

Program: Design, Innov & IP Mgmt (Cert)  
Discontinued  
Design, Innov & IP Mgmt (Cert) Certification

Appears as "Discontinued" whether the certificate is completed or not

Transfer Credits

Transfer Credit from Case Western Reserve University  
Applied Toward Design, Innov & IP Mgmt (Cert) Record

Course	Description	Fall 2011	Attempted	Earned	Grade	Points
MIDS 420A	Design In Mgmt: Concept & Prac			3.00	A	
LAWS 367-1	Commercialization & IP Mangement			3.00	B	
Course Trans GPA:	3.500	Transfer totals:	6.00	6.00		21.000

Transfer Credit from Case Western Reserve University  
Applied Toward Design, Innov & IP Mgmt (Cert) Record

Course	Description	Spring 2012	Attempted	Earned	Grade	Points
MIDS 420B	Design In Mgmt: Concept & Prac			3.00	A	
LAWS 367-1	Commercialization & IP Mangement			3.00	B	
Course Trans GPA:	3.500	Transfer totals:	6.00	6.00		21.000

Beginning of Nondegree Record

Career Totals						
Cum GPA:	3.500	Cum Totals	Attempted 12.00	Earned 12.00	Average 12.00	Points 42.000
Total Credits Earned:	12.00					

End of Nondegree Record

# Guidelines to Create a University Certificate

**Rationale:** There is growing desire to notate both participation in and completion of certificate programs on the university transcript

For university-level recognition to occur:

- formal process for approving certificate programs
- defining and approving criteria and standards for such programs

Committee (formed 03/2016): Lynmarie Hamel (lead), Don Feke, Amy Hammett, Jeremy Naab, Nancy Issa , Paul MacDonald

This document:

- defines the different types of University certificates that may be offered at CWRU
- establishes the minimum requirements for each type of University certificate to be officially recognized by CWRU
- it DOES NOT eliminate existing certificates or prevent the development of new certificates that do not meet these new criteria (non-University certificates)

# Guidelines to Create a University Certificate

## Types of University Certificates

Graduate

Post-Baccalaureate

Professional Certification

## General Minimal Requirements

minimum of 15 credit hours

minimum GPA of 3.0

reviewed by School, FSCGS (post-bac exception), FS Exec Comm, and FS  
must appear in General Bulletin

**Five Year Academic Calendar (2018 – 2023)**

<b>FALL</b>	<b>2018-2019</b>	<b>2019-2020</b>	<b>2020-2021</b>	<b>2021-2022</b>	<b>2022-2023</b>
Registration (and Drop/Add) Begin (UG)	Apr 9	Apr 8	Apr 6	Apr 5	Apr 4
Classes Begin	Aug 27	Aug 26	Aug 24	Aug 23	Aug 29
Late Registration Fee (\$25) Begins	Aug 28	Aug 27	Aug 25	Aug 24	Aug 30
Labor Day Holiday	Sep 3	Sep 2	Sep 7	Sep 6	Sep 5
Late Registration and Drop/Add End	Sep 7	Sep 6	Sep 4	Sep 3	Sep 9
Deadline Credit/Audit (UG)	Sep 7	Sep 6	Sep 4	Sep 3	Sep 9
Fall Break	Oct 22/23	Oct 21/22	Oct 19/20	Oct 18/19	Oct 24/25
Mid-Semester Grades Due (UG)	Oct 22	Oct 21	Oct 19	Oct 18	Oct 24
Deadline for removal of prev. term "I" grades (UG)	Nov 9	Nov 8	Nov 6	Nov 5	Nov 11
Deadline Credit/Audit (G)	Nov 9	Nov 8	Nov 6	Nov 5	Nov 11
Deadline for Class Withdrawal and P/NP (upperclass UG)	Nov 9	Nov 8	Nov 6	Nov 5	Nov 11
Registration for Spring Begins (UG)	Nov 12	Nov 11	Nov 9	Nov 8	Nov 14
Thanksgiving Holidays	Nov 22/23	Nov 28/29	Nov 26/27	Nov 25/26	Nov 24/25
Deadline for Class Withdrawal and P/NP (first year UG)	Dec 7	Dec 6	Dec 4	Dec 3	Dec 9
Deadline for removal of prev. term "I" grades (G)	Dec 7	Dec 6	Dec 4	Dec 3	Dec 9
Last Day of Class	Dec 7	Dec 6	Dec 4	Dec 3	Dec 9
Reading Days	Dec 10, 14	Dec 9, 13	Dec 7, 11	Dec 6, 10	Dec 12, 16
Final Exams Begin	Dec 11	Dec 10	Dec 8	Dec 7	Dec 13
Final Exams End	Dec 19	Dec 18	Dec 16	Dec 15	Dec 21
Final Grades Due by 11:00 am	Dec 21	Dec 20	Dec 18	Dec 17	Dec 23
Fall Awarding of Degrees	Jan 18 (2019)	Jan 17 (2020)	Jan 15 (2021)	Jan 14 (2022)	Jan 20 (2023)
<b>SPRING</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
Registration (and Drop/Add) Begin (UG)	Nov 12 (2018)	Nov 11 (2019)	Nov 9 (2020)	Nov 8 (2021)	Nov 14
Martin Luther King Jr. Holiday	Jan 21	Jan 20	Jan 18	Jan 17	Jan 16
Classes Begin	Jan 14	Jan 13	Jan 11	Jan 10	Jan 17
Late Registration Fee (\$25) Begins	Jan 15	Jan 14	Jan 12	Jan 11	Jan 18
Late Registration and Drop/Add End	Jan 25	Jan 24	Jan 22	Jan 21	Jan 27
Deadline Credit/Audit (UG)	Jan 25	Jan 24	Jan 22	Jan 21	Jan 27
Mid-Semester Grades Due (UG)	Mar 11	Mar 9	Mar 8	Mar 7	Mar 13
Spring Break	Mar 11-15	Mar 9-13	Mar 8-12	Mar 7-11	Mar 13-17
Deadline for removal of prev. term "I" grades(UG)	Mar 29	Mar 27	Mar 26	Mar 25	Mar 31
Deadline Credit/Audit (G)	Mar 29	Mar 27	Mar 26	Mar 25	Mar 31
Deadline for Class Withdrawal and P/NP (upperclass UG)	Mar 29	Mar 27	Mar 26	Mar 25	Mar 31
Open registration for Summer Begins (UG)	Apr 1	Mar 30	Mar 29	Mar 28	Apr 3
Open registration for Fall Begins (UG)	Apr 8	Apr 6	Apr 5	Apr 4	Apr 10
Deadline for Class Withdrawal and P/NP (first year UG)	Apr 29	Apr 27	Apr 26	Apr 25	May 1
Deadline for removal of prev. term "I" grades(G)	Apr 29	Apr 27	Apr 26	Apr 25	May 1
Last Day of Class	Apr 29	Apr 27	Apr 26	Apr 25	May 1
Reading Days	Apr 30/May 1	Apr 28/29	Apr 27/28	Apr 26/27	May 2/3
Final Exams Begin	May 2	Apr 30	Apr 29	Apr 28	May 4
Final Exams End	May 9	May 7	May 6	May 5	May 11
Final Grades Due by 11:00 am	May 11	May 9	May 8	May 7	May 13
University Commencement	May 19	May 17	May 16	May 15	May 21
<b>SUMMER</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
Classes Begin	Jun 3	Jun 1	Jun 1	Jun 6	Jun 5
Independence Day Holiday	Jul 4	Jul 3	Jul 5	Jul 4	Jul 4
Classes End	Jul 29	Jul 27	Jul 27	Aug 1	Jul 31
Final Grades Due 12:00 noon	Jul 31	Jul 29	Jul 29	Aug 3	Aug 2
Summer Awarding of Degrees	Aug 16	Aug 14	Aug 13	Aug 19	Aug 18

# Provost's Commission on the Undergraduate Experience (CUE) – Preliminary Recommendations: Feedback & Progress

*Report to CWRU Faculty Senate*

Kimberly Emmons, Associate Professor  
of English & Chair of CUE

February 27, 2018



Provost's Commission on the Undergraduate Experience

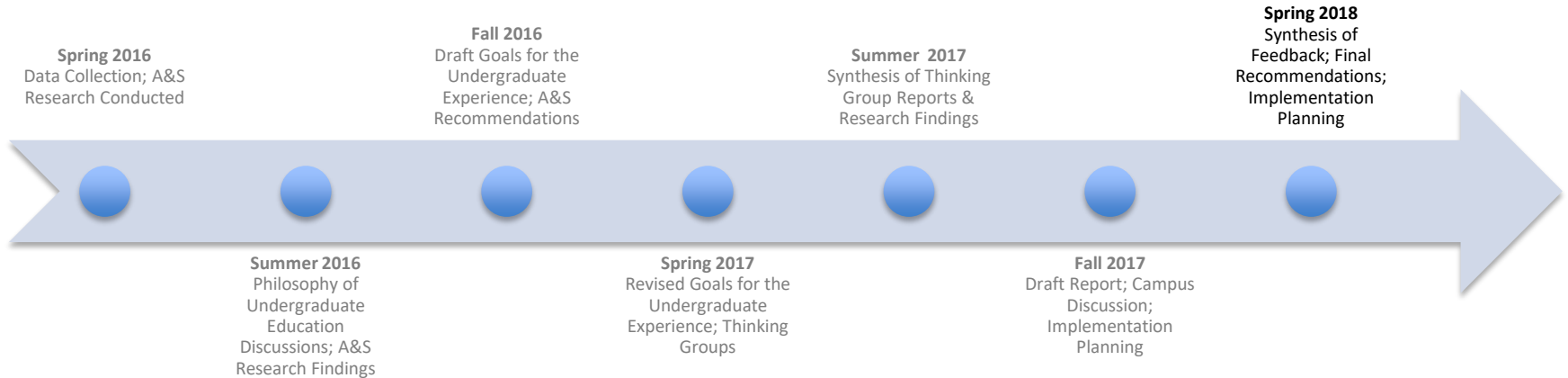
# THE CASE FOR CHANGE

# Indicators of CWRU's Primary Challenge: Campus Ethos

- CWRU's performance statistics on retention are lower than expected
  - 2017 Six-Year Graduation Rate: 82.6% (predicted: 88%)
- CWRU's yield on offers of admission is low & our tuition discount rate is high
  - Fall 2017 Yield: 15.6%; Discount Rate: 55% (domestic students: 62.5%)
- Student satisfaction is low in areas such as: advising, workload, and overall value of the university experience
  - 2016 Seniors' overall satisfaction with their experience: 76%
  - 2016 Seniors who would recommend CWRU to others: 63%

# CUE: Charge & Timeline

*Formulate recommendations to strengthen the overall value, reputation, and desirability of CWRU's undergraduate experience.*



Provost's Commission on the Undergraduate Experience

# **GUIDING PRINCIPLES FOR SUCCESS**

# (Re)Design the *CWRU* Undergraduate Experience

- **UNITY:** Increase coherence and cohesion in the undergraduate experience
  - Design programs to ensure consistent attention to undergraduates
  - Increase opportunities for effective pedagogical/curricular collaboration
- **PREPARATION:** Provide a continuum of mentoring that invites students into the university, facilitates their successes, and prepares them for their futures
  - Leverage institutional data to improve opportunities for students
- **WELLNESS:** Foster balance in and attention to all aspects of students' lives
  - Support students holistically; help them navigate, plan, achieve & thrive

Provost's Commission on the Undergraduate Experience

# MAJOR RECOMMENDATIONS

# CUE Major Recommendations (Fall 2017)

1. Adopt a single University General Education Requirement (UGER) (p. 19; Appendix D)
2. Implement an innovative Explore curriculum (p. 20; Appendix E)
3. Build traditions to celebrate our unique institutional identity (p. 21; Appendix F)
4. Assemble collaborative advising teams (p. 22; Appendix G)
5. Review curricula to reduce stress & increase flexibility for students (p. 23; Appendix H)
6. Foster a thriving, diverse, and inclusive campus community (p. 24; Appendix M)

# Expected Outcomes: Improved Campus Ethos

- Students will feel more connected to (and supported by) CWRU
- More students will have the overall experience that our best and most successful students currently have
- More students will recommend CWRU to peers
- CWRU will be more appealing; more students will see CWRU as their first choice
- Student retention and graduation rates will improve
- Students will be more successful at CWRU and after graduation
- Revenue to university and schools will go up



CUE Major Recommendations

# FEEDBACK & PROGRESS

# 1. University General Education Requirements (UGER)

Explore Curriculum

Intellectual Diversity

Communication/Critical Thinking

Wellness

Capstone

Faculty governance, recognizing disciplinary expertise



# 1. University General Education Requirements (UGER)

Explore Curriculum

Intellectual Diversity

Communication/Critical Thinking

Wellness

Capstone

Faculty governance, recognizing disciplinary expertise

## Feedback: Mixed

- Support for a unified UGER
- Multiple perspectives on content, including how to deliver skills-based courses (writing, critical thinking) and how to define Intellectual Diversity categories

## Progress: In Process

- FSCUE & CUE continuing discussion

## 2. Explore Curriculum



Programs (lectures, experiential learning opportunities, etc.) invite students to discover and deepen their understanding of what different forms of disciplinary knowledge can reveal about the world.

## 2. Explore Curriculum

### Feedback: Mixed

- Significant interest in providing hands-on experiences for students in first semester
- Concerns about over-programming
- Confusion over specifics/implementation

### Progress: In Process

- FSCUE & CUE continuing discussion

Programs (lectures, experiential learning opportunities, etc.) invite students to discover and deepen their understanding of what different forms of disciplinary knowledge can reveal about the world.

### 3. CWRU Traditions: Celebrate Community

# You Are  
Welcome  
HereCWRU

Spread the #YouAreWelcomeHereCWRU Message



**CWRU Day (Fall):** Welcome new first-year students with community/team projects and celebration

**Capstone Day: (Spring):** Celebrate accomplishments of seniors by honoring capstone projects.

## 3. CWRU Traditions: Celebrate Community

### Feedback: Positive

- General support for both CWRU Day and Capstone Celebration Day
- Concern about losing contact hours in academic courses

### Progress: In Process

- FSCUE & CUE continuing discussion

**CWRU Day (Fall):** Welcome new first-year students with community/team projects and celebration

**Capstone Day: (Spring):** Celebrate accomplishments of seniors by honoring capstone projects.

## 4. CWRU Advising Teams

**Academic Advisor(s):** provides mentoring & disciplinary guidance; advisors assigned at matriculation

**Undergraduate Experience Coordinator (UEC):** provides holistic guidance, wellness coaching, career connections, coordinates “team”





## 4. CWRU Advising Teams

**Academic Advisor(s):** provides mentoring & disciplinary guidance; advisors assigned at matriculation

**Undergraduate Experience Coordinator (UEC):** provides holistic guidance, wellness coaching, career connections, coordinates “team”

### Feedback: Negative

- Universal alarm about perceived cost
- Strong desire to increase TT faculty
- Need for resources to improve faculty advising & mentoring

### Progress: In Process

- Student Success Planning Group formed (Administration + Faculty)
- FSCUE & CUE continuing discussion

## 5. Curricular Review



Focus on **flexibility** (UGER + Major + Unrelated Minor) and **streamlining** requirements where possible.

Develop **multiple pathways** to complete major requirements.

Focus on **first-year experience** & integration of **post-college planning**.

# 5. Curricular Review

## Feedback: Mixed

- Support for more flexibility, but concerns about *how* to create curricular space
- Calls for resources to support the time/effort needed
- Confusion over the relationship between Intellectual Diversity & Unrelated Minor

## Progress: In Process

- FSCUE & CUE continuing discussions

Focus on **flexibility** (UGER + Major + Unrelated Minor) and **streamlining** requirements where possible.

Develop **multiple pathways** to complete major requirements.

Focus on **first-year experience** & integration of **post-college planning**.

## 6. Foster Thriving, Diverse & Inclusive Community

Recommendations create “breathing space” for community.

Connected advising, curriculum, and post-college planning will give students space and permission to enjoy CWRU.

Continued study of student quality of life and campus ethos.



## 6. Foster Thriving, Diverse & Inclusive Community

Recommendations create “breathing space” for community.

Connected advising, curriculum, and post-college planning will give students space and permission to enjoy CWRU.

Continued study of student quality of life and campus ethos.

### **Feedback: Positive**

- Universal support
- Questions about whether the Major Recommendations will result in a more thriving & inclusive campus

### **Progress: In Process**

- Student Life conducting student focus groups (Spring 2018)

Provost's Commission on the Undergraduate Experience

# WHAT'S NEXT?

# Spring 2018: Synthesis & Final Recommendations

- Formal Written Feedback – Received January 30, 2018
- Faculty Senate Committee on Undergraduate Education (FSCUE) working with CUE to respond to feedback and develop paths forward
- Student Success Planning Group Formed (Administration + Faculty)
- Student Affairs & USG plan to conduct student focus groups to explore campus community opportunities
- CUE Drafting Final Recommendations – Spring 2018

# Spring 2018: Continuing Feedback Opportunities

- Student Focus Groups (led by Student Affairs/FSCUE Student Life Sub-Committee)
- Continuing School/College Consultations
- Collaboration with FSCUE
- Email: [pcue@case.edu](mailto:pcue@case.edu)
- CUE Office Hours: <http://casfaculty.case.edu/kimberly-emmons/cue>



# Provost's Commission on the Undergraduate Experience

## *Membership*

- CAS: Kimberly Emmons (Chair), Jerrold Scott, Lee Thompson, Blanton Tolbert
- CSE: Daniel Lacks, Frank Merat
- FPBSON: Amy Bieda
- WSOM: Robin Dubin
- SOM: Hope Barkoukis
- Support Areas: Richard Bischoff (Enrollment Management), Molly Watkins (International Affairs), Louis Stark (Student Affairs), Jeffrey Wolcowitz (Undergraduate Studies)
- Student Representation: Nishant Uppal ('17), Prince Ghosh ('19),

Garretson Oester ('18)

- Administrative Resources: Donald Feke, Victoria Wright

*(Note: Members were selected by the Provost with input from the Deans.)*