



IRB Expedited and Full Review Application Form

Instructions: Complete this form to request an **expedited IRB review of research involving human participants**. The checklist below is for general guidance to help researchers submit complete application materials and facilitate the review process. Incomplete or unreadable applications will **extend** the IRB review process. If you are collecting data at a hospital, please seek hospital IRB approval prior to Regis College IRB approval. Please note, pilot studies and scale development studies should be submitted to the IRB as well. Please submit an electronic application and all research materials (consent form, surveys, interview guides, etc.) to irb@regiscollege.edu.

A Complete Application Packet Should Include:

- An electronic copy of the IRB application form, research summary, and research instruments. Types of research instruments that should be attached include:
 - Recruitment materials: emails, letters, recruitment scripts, flyers, posters, brochures, etc.
 - Data collection materials: questionnaires, surveys, data collection forms, focus group scripts, interview scripts, etc.
- Signature page with faculty advisor and student signatures
(Approval will be withheld without signatures.)
- Copies of CITI training certificates **for all key research personnel who will interact with subjects or collect data**
- Consent forms(s)—You must use the Regis College IRB Informed Consent Template found on the Regis College IRB website** when creating your informed consent form(s).
- If minors (under 18) will be research participants, you must create a Child Assent Form and a Debriefing Form using the templates found on the Regis College IRB website.**
- All appendices are labeled and are in order.

NOTE: DO NOT REMOVE THE HEADINGS FROM THIS APPLICATION!

Student Researchers:

- Faculty research advisor was consulted in the study design and has reviewed and signed the application.

Research in Hospitals or HIPAA-Covered Entities

- Submit copies of the IRB approval letter and IRB approved consent form(s) from the participating institution(s).

Research in Public Schools:

- Submit copies of the permission letter to perform research from each school principal via email.
- Submit copies of IRB approval if the school has an IRB.

Research at sites other than Regis College:

- Submit copies of the site permission letter to perform research from administrator via email.
- Submit copies of IRB approval if the site has an IRB.

Federally funded research:

 Wait until you have been funded before submitting an IRB Application.

- Submit documentation of funding status with this protocol application.
- Submit a complete copy of the federal grant/contract proposal including face page.



IRB Expedited and Full Application Form

For Initial IRB Review Only

Regis College Institutional Review Board
Office of Academic Affairs
235 Wellesley Street
Weston, MA 02493-1571
(781) 768-7430
email: irb@regiscollege.edu

I. Study Title:

(If funded, the study title must match the sponsored title.)

Today's Date:

II. Principal Investigator Information

A. Name of Principal Investigator	B. Are You? (Please check)		
	<input type="checkbox"/> Faculty		
C. Mailing Address:	<input type="checkbox"/> Staff		
D. Department:	<input type="checkbox"/> Undergraduate Student		
E. Email address:	<input type="checkbox"/> Graduate Student		
F. Primary Phone Number:	G. Alternate Phone:	<input type="checkbox"/> Postdoctoral fellow	
H. Faculty Advisor's Name:	I. Faculty Advisor's Phone:	<input type="checkbox"/> Other:	
J. Faculty Advisor's E-mail:			

III. Funding

A. None (Go on to Section IV)

Do you plan to apply for funding in the future? Yes No If yes, please explain:

B. University Funded: List source:

C. External, non-federal*: List source and grant number:

D. Federal*: List agency, department, and sponsor's award number:

*Wait until you have been notified that your project will be funded before seeking IRB approval unless otherwise instructed by the funding source. If federal funding is involved, submit documentation of funding status with a complete copy of the funding proposal with this form.

E. Is Regis College the primary awardee for the grant? Yes No If no, please list primary awardee:

F. Are there subcontracts? Yes No If yes please list sub-contractors:

IV. General Study Information

A. Anticipated number of participants:	C. Estimated Project Duration *Start Date: _____ End Date: _____
B. Participant Ages (please check)	D. Why is this project being conducted?
<input type="checkbox"/> 0-7 (requires written parental informed consent and oral child assent) <input type="checkbox"/> 7-17 (requires written parental informed consent and child written assent) <input type="checkbox"/> 18-65 (requires written informed consent) <input type="checkbox"/> 65+ (requires written informed consent)	<input type="checkbox"/> Faculty/Staff Research <input type="checkbox"/> Undergraduate Coursework <input type="checkbox"/> Master's Thesis <input type="checkbox"/> Doctoral Research <input type="checkbox"/> Quality Improvement or Evaluation <input type="checkbox"/> Other: <small>*Project cannot start without IRB approval.</small>
E. Will this study involve long-term follow-up with participants? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe:	
F. Vulnerable Populations (Check if applicable.) <input type="checkbox"/> Minors (under 18 years) <input type="checkbox"/> Pregnant women and fetuses <input type="checkbox"/> Neonates <input type="checkbox"/> Prisoners <input type="checkbox"/> Cognitively impaired (Diminished capacity for consent) Other:	

V. Research Risk

Research must present no more than minimal risk to human participants in order to qualify for expedited review. Minimal risk means that 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." (45 CFR 46.102)

A. Does the research propose greater than minimal risk to participants? Yes* No

*If yes, skip to part **C** of this section.

B. Does the research include prisoners? Yes* No

*If research includes prisoners, the application must be reviewed by the full IRB.

C. Check all procedures that apply to the research:

- (1) Clinical studies of drugs and medical devices.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings; saliva; deciduous teeth at time of exfoliation or extracted during routine care; excreta and external secretions (including sweat); un-cannulated mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples: physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis).
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- (8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new participants, (ii) all participants have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
- None of the above categories apply.

For a comprehensive list of expedited categories see <http://www.hhs.gov/ohrp/policy/expedited98.html>

D. Does this study involve any of the following? (Check all that apply.)

- Deception
- Punishment
- Use of drugs
- Covert observation
- Induction of mental and/or physical stress
- Procedures which may risk physical/mental harm to the participant
- Materials/issues commonly regarded as socially unacceptable
- Information relating to sexual attitudes, sexual orientation, or practices
- Information relating to the use of alcohol, drugs, or other addictive products
- Procedures that might be regarded as an invasion of privacy
- Information pertaining to illegal conduct
- Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
- Information normally recorded in a patient's medical record, which if disclosed could reasonably lead to social stigmatization or discrimination
- Information pertaining to an individual's psychological wellbeing or mental health
- Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community

Please provide details on all procedures checked above: How are they integral to the study?

VI. Research or EBP Summary:

Please insert responses to each question using the topic headers **A-I** below (do NOT attach separate answers for each question – answer ON this form). Be sure to dedicate about 1 page to the review of literature and include 3-5 references at the end of this review. Please use simple language and avoid technical jargon. **Be sure to address each item.**

Note: Grant, thesis, dissertation or course work proposals may **not** be submitted in lieu of the Research Summary because traditional proposals do not include specific information on risks, benefits and detailed informed consent procedures. Please insert responses to each question under each question on this

A. Introduction and Background:

1. State the research, clinical practice, or evaluation question.
2. Provide the scientific or scholarly literature for this study and background on the topic (maximum of one page with 3-5 references).

B. Specific Aims/Study Objectives:

1. List the purpose(s) of the study (What you are hoping to learn or discover as a result of the study?).

C. Materials, Methods, and Analysis (quantitative and qualitative):

1. Describe data collection methods (procedures)—Be specific.
2. Describe the specific materials or tools that will be used to collect the data. Include proposed measures as an appendix.
3. Describe timeline of the procedures and how long each procedure will last.
4. Describe how you will analyze your data based on the modality; describe the analysis type and procedures including statistics and scientific or scholarly justification for the use of these analyses—be specific.

D. Research Population & Recruitment Methods:

Describe:

1. Inclusion and exclusion criteria (What participant traits are needed to be included? What traits exclude participants?) (please put in a list format)
2. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?
3. How did you choose the source of participants or data?
4. Recruitment procedure (if applicable) including who will recruit participants.
5. Tools that will be used to recruit (payment, advertisements and flyers—Attach copies to this application.)

(Note: participant payment beyond \$600 must be reported to the IRS, and this requirement must be added to the consent form. Incentives should not exceed \$50 per participant)

E. Informed Consent Procedure:

Describe:

1. Who will perform the informed consent procedure?
2. How will that person be trained? (previous related coursework, previous experience, one-on-one training with PI or faculty, etc.)
3. How will the prospective participant's competence or understanding of the procedures be assessed? Will participants be asked questions about the procedures or encouraged to ask questions?

F. Confidentiality:

Describe the provisions for participant and data confidentiality:

1. Where will the data be stored, and who will have access to the data and the area (note: data should be kept for a minimum of three years)?
2. How and in what format (hard or electronic copy, identifiable or de-identified) will the data be stored?
3. Will the participants' identities be coded? Will the codes to identify participants be stored with the data? (**Note:** If you are working with a hospital or clinic, please see information on HIPAA and research at <http://privacyruleandresearch.nih.gov/>)

G. Potential Research Risks or Discomforts to Participants:

1. Indicate the type of risk that may result from participation. Consider psychological or emotional risks, social stigma, change in status or employment, physical risks or harms, information risks including breach of confidentiality and any effect loss of confidentiality may have on status, employment, or insurability. If the protocol involves treatment, what are the risks compared to other treatments in terms of "standard of care"? (For example: Psych Referral 24 hours 7 days a week; This study poses minimal risks to participants. Two potential but unlikely risks that you may experience are fatigue and possible emotional distress about the topic. Should the intervention make you feel distressed or upset, please utilize the National Institute of Health link here to access counseling or providers immediately nationwide <https://www.nimh.nih.gov/health/find-help>)
2. Consider the likelihood and magnitude of the risks or discomforts occurring? Are they unlikely or likely to occur, and what effect would the discomforts or risks have on the individual should they occur?

3. How will you minimize risks? Some examples include informed consent, adequate staff training and experience, debriefing, and monitoring adverse effects on participants.

H. Potential Research Benefits to Participants:

1. Indicate the type of benefit that may result from participation. Consider psychological or emotional benefits, learning benefits, physical benefits and discuss if participant will benefit directly or if the benefit is largely to gather generalizable knowledge or provide scientific or social information on a topic that may benefit society. DO NOT OVERSTATE the benefit.

I. Investigator Experience. Please complete the NIH Bio Sketch below for the PI.

BIOGRAPHICAL SKETCH for PI

Provide the following information for the PI and other significant contributors.
Follow this format for each person. **DO NOT EXCEED ONE PAGE.**

NAME:

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions and Honors

C. Contributions to Science

D. Additional Information: Research Support and/or Scholastic Performance

VII. Informed Consent

A. The informed consent document should include all required elements of consent (See the Regis IRB informed consent template on our website and/or below). **Confirm that each element is included in your consent form:**

- A statement that the study involves research
- A statement that they are being asked to participate in research and how they were selected to participate
- The purpose of the research in lay terms (in language understandable to the participants)
- The expected duration of the participants' participation (e.g., "You will be asked to complete a survey every month for 1 year.")
- The total time commitment of participation in the procedures (e.g., "The survey will take 20 minutes to complete.")
- A brief but complete description of all procedures to be followed (Invasive biological, clinical, or behavioral interventions require specific descriptions of the procedure. If research includes treatment, describe which procedures are experimental and alternatives to those procedures.)
- The benefits to the participant or others that are reasonably expected from the research
- The risks or discomforts that are reasonably expected from the research and a statement that "There may be unknown risks."
- A statement describing any payments for being in the study or that there is no payment for being in the study
- A statement indicating that there is no cost to the participant for being in the study
- A statement that participation is entirely voluntary and may be discontinued at any time
- A statement that withdrawal from participation will not result in denial of entitled benefits or harm the participant's relationship with Regis
- A statement of confidentiality describing how the participants' personal information will be kept private
- A statement that provides the participants with a contact at the institution who may be reached if injury occurs or confidentiality is breached
- The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness.

Note: Individuals with added protections require both permission of a legal representative and assent of the individual.



**Regis College [school or department name]
Informed Consent to Participate in [title of study]
Researcher: [name of principal investigator (PI)]**

Introduction

Please read this form carefully. You are being asked to participate in a research study of [Insert a general statement about the study]. You were selected to participate in this study because [List inclusion criteria]. You are not eligible to participate if [List exclusion criteria]. Please ask any questions you may have before you agree to participate in the study.

Purpose of the Study

The purpose of this study is [Explain the research question and purpose in simple language].

Description of Study Details

If you agree to participate in this study, we would ask you to [Explain procedures and tasks. Identify any procedures that are experimental. Describe the length of time for participation, frequency, and duration of procedures, etc. For example, if participants will be interviewed during the study you would describe: how many interviews, the length of each interview, and/or where the interview will take place. Also, please provide the questions being asked].

Benefits of Being in this Study

The benefits of being in this study are [State the anticipated benefits the research will produce for society and/or the participants. If there are no expected benefits, state as such.]

Risks and Discomforts of Being in this Study

The study has the following risks. First, [Explain the first risk, its likelihood, and how it will be minimized]. Second, [Explain the second risk, its likelihood, and how it will be minimized]. Third, . . . [If there are no foreseeable risks, state that there are no risks beyond what the participant experiences in daily life].

To the extent the study requires or involves physical interaction with other people or otherwise occurs within space shared with other individuals there is a risk of transmission of and/or infection by communicable disease including, but not limited to, the 2019 Novel Coronavirus (COVID-19). The study will be conducted in compliance with local, state, and federal guidance related to COVID-19, but despite these efforts the risks of transmission and/or infection cannot be completely eliminated.

Payments

You will receive the following payment for being in the study: [Explain the amount of payment or other reimbursement information (e.g., class points, tokens, donations, etc.), as well as when payment and/or reimbursement will occur and in what cases payment will not occur, if any].

If there is no payment, state: [There is no payment for being in this study].

Cost

There is no cost to you for being in this research study.

Choosing to participate in the Study and Choosing to Quit the Study

It is your choice to participate in this study. If you choose not to participate in this study, it will not affect your current or future relations with Regis. You are free to decline to answer questions or quit at any time, for any reason. There is no penalty for not taking part or for quitting. [If you are using students, you must include a statement that participating or not participating in the study will have no impact on their academic status. If you are using employees, you must state that participating or not participating in the study will have no impact on their employment status. Explain consequences (e.g., adjusted monetary benefits) of early withdrawal, if any.]

Getting Dismissed from the Study

The researcher may dismiss you from the study at any time for the following reasons: [Include the reasons, for example, “(1) it is in your best interests (e.g., side effects or distress), (2) you have not followed the study rules, or (3) the study sponsor decided to end the study.”].

Privacy

The records of this study will be kept private. This study is [Select one: anonymous, confidential, or open]. [Explain how information about the participants will be protected, for example, “Research records will be kept in a locked file” or “All electronic information will be coded and secured using a password-protected file.” Explain who will have access to the study records, and when and how they will be destroyed. Responses are anonymous when the researcher does not know the identity or any identifying information about who wrote them. If you are keeping a list connecting participants’ names to ID numbers, explain how you will keep that information protected and separate from your data analysis. If applicable, state that the responses are meant to be combined with other participants’ data and are not meant to gather information about specific individuals.] No published reports will include any information that will make it possible to identify you.

Contacts and Questions

The researcher conducting this study is: [PI's name]. The researcher will be available to answer any questions about the study at: [phone number and email address]. If you have questions or concerns about your rights, you may contact the Regis Institutional Review Board Chair:

Dr. Colleen C. Malachowski, PhD
781-768-7373
colleen.malachowski@regiscollege.edu

Statement of Consent [Choose only one statement according to the type of consent form.]

[Adult Participant Informed Consent]

I have read this form (or have had it read to me). I have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I understand the risks and discomforts associated with the above study and understand that I may quit the study at any time without penalty.

[Parent/Guardian Informed Consent for Participants Ages 17 and Younger]

I have read this form (or have had it read to me). I have been encouraged to ask questions. I have received answers to my questions. I give my consent for my child to participate in this study. I understand the risks and discomforts associated with the above study and understand that my child may quit the study at any time without penalty.

If applicable to your study:

I agree to be audio and/or video recorded (Check One):

Yes No

Signature(s)/Date [Delete any that do not apply to your protocol.]

[Adult Participant Informed Consent]

Participant Printed Name: _____

Participant Signature: _____ Date: _____

[Parent/Guardian Informed Consent for Participants Ages 17 and Younger]

Study Participant Printed Name: _____

Parent/Guardian Printed Name: _____

Parent/Guardian Signature: _____ Date: _____

[Interpreter for Non-English-Speaking Participants]

Interpreter Printed Name: _____

Interpreter Signature: _____ Date: _____

[Participant's Legal Representative]

Participant Printed Name: _____

Legal Representative Printed Name: _____

Legal Representative Signature: _____ Date: _____

Witness Printed Name: _____

Witness Signature: _____ Date: _____

- C.** The Regis IRB recommends that the reading level of the informed consent document should be no higher than an 8th grade level. The IRB recognizes that some consent forms are of such a technical nature that it may not be possible to keep to an 8th grade reading level. The comprehension level of the consent document must be verified to ensure it is consistent with the comprehension level of the participants. Please use the Flesch-Kincaid Grade Level score to verify the comprehension level and insert it below. **Instructions for assessing the Flesch-Kincaid Grade Level score using MSWord are on the first page of the informed consent and child assent templates, or you can paste your text into www.readability-score.com .** (After pasting the text in the box, place the cursor at the end of the text and hit "Enter" or you will not get a reading from the website.)

Flesch-Kincaid Grade Level Score:

VIII. Research Staff (e.g., PI, Co-PI, Research Assistant, etc.). Please attach a list and submit CITI certificates for all personnel who will interact or collect data. The CITI Training is required.

Name and Credentials	Date of CITI Training Certificate	Research Role	University/Department

IX. Performance Sites:

If the institution has an IRB, IRB approval may have to be received from that institution as well as Regis College. If the institution does not have an IRB, the institution must authorize or provide permission for the research activities (Please include a site permission letter from an institutional official – these letters should be signed by an official on the institutions letterhead. If you are using social media sites, please include permission from the administrator of that site). If you are collecting data at a hospital with an IRB, seek hospital approval prior to submitting the Regis IRB initial application form. Please also include any data use agreements and/or review agreements.

Name of Institution	Date of IRB Approval

X. Acknowledgement

SUBMISSION OF A PROPOSAL TO THE REGIS COLLEGE IRB REQUIRES THAT THE PRINCIPAL INVESTIGATOR (AND MENTOR IF THE PI IS A STUDENT OR FELLOW) READ THE DEFINITION OF "SCIENTIFIC MISCONDUCT" AND ANSWER ALL "CONFLICT OF INTEREST" QUESTIONS BELOW.

A. Scientific Misconduct

"Scientific Misconduct" shall be considered to include:

1. Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out, or reporting results from research;
2. Material failure to comply with federal requirements for the protection of human participants, researchers and/or the public;
3. Failure to meet other material legal requirements governing research;
4. Failure to comply with established standards regarding author names on publications;
5. Failure to adhere to issues of confidentiality as provided in the participant consent form, the study protocol, and as outlined in the Code of Federal Regulations ([45 CFR 46](#)).

B. Conflict of Interest

1. Are you or any member of your immediate family (spouse or domestic partner and/or dependent children) an officer, director, partner, trustee, employee, advisory board member, or agent of any of the following : (Check all that apply.)
 - An external organization funding this project
 - Any external organization from which goods and services will be obtained under this project (including those to which you may be subcontracting a portion of the project work)
 - Any external organization whose financial condition could benefit from the results of this project
 - Any external organization having business dealings in an area related to the work under this project
2. Are you or any immediate family member the actual or beneficial owner of more than five percent (5%) of the voting stock or controlling interest of (a) the external organization funding this project, (b) any external organization from which goods and services will be obtained under this project (including those to which you may be subcontracting a portion of the project work), (c) any external organization whose financial condition could benefit from the results of this project, or (d) any external organization having business dealings in an area related to the work under this project? Yes No
3. Have you or any member of your immediate family derived income within the past year, or do you or any member of your immediate family anticipate deriving income, exceeding \$10,000 per year from : (Check all that apply.)
 - An external organization funding this project
 - Any external organization from which goods and services will be obtained under this project (including those to which you may be subcontracting a portion of the project work),
 - Any external organization whose financial condition could benefit from the results of this project
 - Any external organization having business dealings in an area related to the work under this project

Do not include funds that would pay your university salary under a sponsored project budget.

***If you checked any of the above, please specify the extent of involvement:**

4. For those projects funded by any external entities, do you have a current, up-to-date Conflict of Interest Disclosure on file with the Office of Academic Affairs that describes this financial relationship? Yes No (If no, you must submit an undated COI disclosure before IRB review.)

SIGNATURES**SIGNATURE OF PRINCIPAL INVESTIGATOR**

The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Regis policies regarding protections of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.

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Printed Name of Principal Investigator	Signature of Principal Investigator	Date
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SIGNATURE OF FACULTY RESEARCH SUPERVISOR--REQUIRED FOR STUDENT RESEARCH

By signing this form, the faculty research supervisor attests that s/he has read the attached protocol submitted for Regis IRB review and agrees to provide appropriate education and supervision of the student investigator and share the above Principal Investigator responsibilities.

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Printed Name of Faculty Research Supervisor	Signature of Faculty Research Supervisor	Date
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SIGNATURE OF DEPARTMENT CHAIR OR ASSISTANT/ASSOCIATE DEAN--REQUIRED FOR FACULTY RESEARCH ONLY

Your signature below affirms that you have been informed of the research.

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Printed Name of Department Chair or Dean	Signature of Department Chair or Dean	Date
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