UNIVERSITY OF PUERTO RICO
MEDICAL SCIENCES CAMPUS
SCHOOL OF MEDICINE
INTERNAL MEDICINE
PROGRAM

RESEARCH POLICY AND PROCEDURE MANUAL

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1. Policy Statement

It is the policy of the program that research coordinated by and conducted within the residency is carried out according to applicable institutional and federal policies.

2. Purpose

This manual guides Internal Medicine residents in the procedures for clinical research and scholarly activities. Research, as defined within this manual, encompasses a systematic investigation to generate or contribute knowledge that can be applied beyond the specific study population or situation.

The systematic investigation process outlined in this handbook entails adhering to a predetermined plan to carefully examine a specific issue, test a hypothesis or research question, or develop innovative theories. This process may involve:

2.1. Collection of Quantitative or Qualitative Data: Gathering data through various methods, such as clinical case studies, surveys, clinical data abstractions, tests, evaluations, interviews, focus groups, or observational studies.

2.2. Experimental Designs: Conducting research using experimental designs, including clinical trials, to evaluate interventions or treatments.

2.3. Observation of Individual or Group Behavior: Observing and analyzing behaviors of individuals or groups to gain insights and draw conclusions.

2.4. Secondary analysis: Use existing research data to find the answer to a question different from the original work.

3. Dissemination of Scholarly Activities

Scholarly dissemination practices refer to the strategies and methods to share research findings and outcomes with relevant audiences. Dissemination aims to communicate research results effectively to maximize their impact, facilitate knowledge transfer, and promote the utilization of research findings in various contexts.

Research dissemination materials refer to the tangible resources or outputs created to disseminate research findings. These materials can take various forms depending on the target audience, purpose, and mode of communication. Some common examples of research dissemination materials include:

3.1. Research Manuscripts and Journal Articles: These are scholarly publications that present research findings, methodologies, and analyses in a detailed and formal format. They often undergo a peer-review process before being published in academic journals.

3.2. Conference Presentations: Researchers may present their findings at academic conferences through oral presentations, poster presentations, or symposiums. Conference presentations allow researchers to engage with peers, receive feedback, and disseminate their work to a broader audience.

3.3. Reports and Policy Briefs: Research reports and policy briefs are concise summaries of research findings targeted toward policymakers, government agencies, or organizations.

They aim to communicate research results in a format that is accessible, informative, and actionable for decision-makers.

3.4. Media Engagement: Researchers may engage with the media to disseminate research findings to a broader public audience. This can involve press releases, interviews, or news articles that communicate research outcomes in a way that is accessible and relevant to the general public.

Dissemination of scholarly work affiliated with the residency program, such as abstracts, posters, or presentations, requires review and approval by a faculty member determined as the senior researcher or faculty member. This ensures that the materials align with the program's guidelines, ethical considerations, and professional standards, thereby upholding the integrity and reputation of the residency program.

4. Research Assistant Program Director

The role of a Research Assistant Program Director (RAPD) is critical in overseeing and managing the research conducted within the residency. Generally, the RAPD has the following key roles:

4.1. Abstract Review: Responsible for reviewing abstracts from residents before their submissions. They assess the abstracts' quality, relevance, and scientific merit to determine their suitability for presentation at conferences, symposiums, or other academic events.

4.2. Manuscript Review: Critically evaluates the quality, validity, and relevance of the research presented in the manuscripts. Assesses the scientific merit of the manuscripts by examining the research design, methodology, data analysis, and interpretation of results.

4.3. Presentation Review: Review residents' presentation materials, such as oral presentations or posters. They evaluate the organization, coherence, and effectiveness of the visual aids and guide presenting the research findings in a clear and engaging manner.

4.4. Presentation Skills Development: Offer guidance and support to residents in developing their presentation skills. They may provide coaching on effective oral communication, public speaking, and engaging the audience. This includes helping residents structure their presentations, practice delivery, and address potential questions or challenges.

4.5. Conference Selection: In collaboration with residents, the Program Director may assist in selecting appropriate conferences or events for presenting their research. They consider factors such as the conference theme, target audience, prestige, and relevance to the research area, ensuring that residents have opportunities to showcase their work to the appropriate audience.

4.6. Orientation and training: Oversee the orientation and training of residents. They ensure

that residents receive the necessary information, resources, and training to familiarize them with the research curriculum's objectives and procedures.

4.7. Supervision and Mentorship: Provides supervision and mentorship to residents. This involves setting performance expectations, providing ongoing feedback and guidance, addressing challenges or concerns, and fostering a supportive and productive research environment.

4.8. Research Compliance and Ethics: Ensures residents adhere to ethical standards and comply with relevant regulatory requirements. They promote research integrity, oversee ethical review processes, and ensure research activities follow applicable laws, guidelines, and institutional policies.

4.9. Research Collaboration and Networking: Facilitates research collaboration and networking opportunities for residents. They encourage participation in conferences, workshops, and other professional development activities and support the dissemination of research findings through presentations and publications.

4.10. Progress Evaluation and Career Development: Periodically conducts progress evaluations of residents, providing feedback on their progress, identifying areas for improvement, and recognizing achievements. They also support career development by guiding residents' professional growth and identifying opportunities for further education, training, or advancement.

4.11. Collaboration with Stakeholders: Collaborates with various stakeholders, including faculty members, researchers, institutional administrators, and external partners. They foster effective communication, promote interdisciplinary collaboration, and ensure alignment with the organization's research goals and strategic initiatives.

In collaboration with designated faculty members, the RAPD is responsible for reviewing and approving dissemination materials, such as abstracts, posters, or presentations, before they are shared with external audiences. For details about the procedures for approval, see section 6 of this manual.

5. Travel to Academic and Professional Meetings

Travel within a residency program offers valuable opportunities for residents to enhance their knowledge, network with peers and experts in their field, and contribute to the advancement of medical or research practices. This policy aims to ensure that residents can participate in conferences, presentations, workshops, or other educational activities while adhering to the program's guidelines, budgetary constraints, and institutional regulations.

5.1. Approval Process: All travel plans must be approved in advance by the Program Director. Residents must submit a travel request detailing the purpose, dates, and destination for the proposed trip within 2 weeks of abstract acceptance. Travel arrangements made without

the approval of the Program Director are not authorized and are not eligible for reimbursement. The steps required for approval are the following:

5.1.1. Send the travel request to the Chiefs of Residents, with a copy to the Program Director, RAPD, and Residency Administrator, notifying them that your work has been accepted, along with the date and time of your presentation. The official acceptance letter must be included in the request.

5.1.2. The Chiefs of Residents will evaluate the request and determine the days allotted for travel.

5.1.3. The resident is not authorized to book flights and accommodation until the Chiefs of Residents have informed you of the available dates for travel.

5.1.4. Residents will be responsible for coordinating with the Chiefs of Residents to ensure that rotation responsibilities are not affected.

5.2. Eligibility for Reimbursement: Travel support for conference presentations or other academic activities may be eligible for reimbursement. Residents should consult the residency program guidelines or specific funding sources to determine the reimbursement criteria and limits.

5.3. Pre-Travel Planning: Residents are responsible for making all necessary travel arrangements, including booking flights, accommodation, conference registration, and ground transportation.

5.4. Travel Expenses: Residents are expected to be mindful of travel expenses and adhere to budgetary guidelines. Reasonable and necessary expenses related to travel, such as airfare, accommodation, ground transportation, and meals, may be eligible for reimbursement.

5.5. Documentation: Residents must retain all relevant travel receipts and documentation, including boarding passes, hotel invoices, and meal receipts, for reimbursement purposes. Original copies or electronic copies of receipts may be required.

5.6. Reimbursement Process: Residents should submit a travel request and the necessary supporting documentation to the Residency Coordinator no later than 20 days before travel. The request should include evidence such as airfare, accommodation, conference registration, and the abstract acceptance letter.

It is important for residents to familiarize themselves with the specific travel policy and guidelines established by their residency program. These policies ensure the appropriate use of resources, financial accountability, and compliance with institutional regulations.

6. Abstract Submission

This policy serves as a framework for residents to submit their abstracts for consideration in conferences, symposiums, or other academic events. The abstract submission policy sets forth the

criteria for eligibility, topics, deadlines, and the submission process. Furthermore, the policy emphasizes ethical considerations, authorship guidelines, and the importance of obtaining appropriate consent and protecting patient confidentiality.

6.1. Eligibility: Residents in all stages of training are eligible to submit abstracts.

6.2. Scope and Topics: Acceptable topics for abstract submissions include clinical case reports, research studies, quality improvement projects, medical education initiatives, or other relevant areas of internal medicine.

6.3. Deadlines and Submission Process: The abstract must be reviewed and approved by the RAPD prior to submission. Residents are responsible for sending the abstract to the RAPD, Dr. Arelis Febles-Negrón and the senior author (attending faculty or principal investigator) at least 10 days days prior to the anticipated date of submission. The email should provide details on the conference submission process, such as the required format (e.g., word limit, specific template), submission deadlines, and any supporting documents or additional information needed. Clinical cases must undergo review and approval by the attending faculty member who should be included in all communications regarding the abstract.

6.4. Review and Approval of Final Draft: The RAPD and Dr. Arelis Febles-Negrón will review the abstract before submission and provide necessary feedback. The criteria for evaluation include factors such as scientific rigor, relevance, clarity, and potential impact. It is a requirement to obtain approval for the final version of the abstract before submitting it to the conference. If changes are requested, residents must return the edited abstract within 2 days of notification.

6.5. Notification and Presentation Format: Residents will be notified of the status of their abstracts (accepted, rejected, or requiring revisions). Residents are not authorized to submit abstracts without the program's approval. Expect to receive notification within 7 days and be attentive to respond to change requests if necessary. The Program Director (PD) and the senior author (Attending faculty or PI) will be copied in this notification.

6.6. Ethical Considerations and Consent: While safeguarding patient confidentiality is crucial for all research procedures and dissemination practices, it is important to note that certain meetings require documented evidence of patient consent before abstract submission. Therefore, it is essential to obtain appropriate patient consent and adhere to ethical guidelines when submitting clinical case reports or any other research materials. Proof of patient consent may not be required if the case report does not include identifying information; however, some journals and scientific meetings require informed consent for all case reports before acceptance or publishing. Authors are responsible for consulting the journal or meeting requirements to determine if they have a specific consent form. An example of a case report consent form can be found in Appendix 1

6.7. Findings discrepancy: Due to the time lapse between abstract submission and conference presentation, it is common for abstracts to include interim or preliminary findings. However, it is possible that by the time of the presentation, certain details may have changed. To address this, we recommend that authors notify the conference of whether there are substantial changes in research findings that impact the conclusions.

6.8. Conference Abstract Withdrawal: Authors may not be able to present an accepted abstract for multiple reasons. Authors should carefully consider the validity and significance of their reasons for abstract withdrawal. Funding and other predetermined considerations, such as rotation hours, authorship, ethical concerns, and incomplete or inconclusive research must be addressed before abstract submission. For example, to fulfill 80% of the rotation, the resident may not be absent for more than 5 days. However, unforeseen circumstances that are beyond the control of the authors, such as illness, and personal emergencies may serve as valid reasons for abstract withdrawal. It is important to note that some conferences may consider co-author replacement under exceptional, unavoidable circumstances. The replacement of the presenting author is preferable to withdrawal. However, in cases where abstract withdrawal is deemed necessary, residents are advised to thoroughly review the guidelines and policies of each conference. Residents are required to communicate the intention of withdrawal with the RAPD and timely notification to the conference organizers to minimize disruptions to the conference program and allow for appropriate adjustments. Authors who fail to present their poster or give their talk without withdrawing their abstract may forfeit the right to present in the future.

6.9. Encore Submissions: An encore is an abstract submitted for a conference presentation that reports on research or scholarly work previously presented at another conference or published in a journal. Although encore abstract submissions are allowed and encouraged under certain circumstances, conference organizers may enforce limitations on the number of encore presentations allowed from a single research project or group of authors. Preference may be given to new, original research over encore presentations during the selection process. Residents are responsible for determining if the conference allows for the submission of encore abstracts. Authors must disclose the previous conference or publication where the research was presented or published.

7. Health Information Privacy

It is important to handle identifiable information with utmost care and ensure compliance with privacy regulations, such as the Health Insurance Portability and Accountability Act (HIPAA). Researchers and healthcare professionals should take appropriate measures to de-identify or anonymize data, when possible, to minimize the risk of unintended identification.

Identifiable information, in the context of healthcare and research, refers to data or characteristics that can be used to identify an individual directly or indirectly. Identifiable information includes, but is not limited to, the following:

6.9.1.1. Personal Identifiers: Any data elements that directly identify an individual, such as their name, social security number, address, date of birth, or telephone number.

6.9.1.2. Demographic Information: Information related to an individual's characteristics that, in combination, could potentially identify them, such as gender, race, ethnicity, marital status, or occupation.

6.9.1.3. Health Information: Any data related to an individual's physical or mental

health, including medical conditions, treatments, medications, test results, or other medical history. This includes both past and present health information.

6.9.1.4. Genetic Information: Data related to an individual's genetic characteristics, including their DNA sequences, genetic test results, or family medical history that may be used to identify them or their relatives.

6.9.1.5. Biometric Data: Unique biological or physiological identifiers, such as fingerprints, retinal scans, voiceprints, or DNA profiles, that can be used to identify an individual.

6.9.1.6. Geographic Information: Specific geographic or locational data that can identify an individual, such as their exact address, GPS coordinates, or specific landmarks associated with them.

6.9.1.7. Photographs: Photographs can be considered identifiable information if they contain features or characteristics that can be used to identify an individual. Photographs that directly show a person's full face, unique physical traits, or other identifying information can potentially be used to identify that individual. When using photographs for research or publication purposes, researchers must obtain appropriate consent from the individuals involved and follow any institutional or legal requirements regarding the use and disclosure of photographs. To minimize the risk of unintended identification, researchers may choose to de-identify or anonymize photographs by removing or blurring identifiable features such as eyes, including eyebrows, tattoos, birthmarks, or other distinguishing marks.

6.9.1.8. Any Other Unique Identifiers: Any other data or combination of data that can be used to directly or indirectly identify an individual, such as patient identification numbers, health insurance numbers, or membership IDs.

8. Consequences of noncompliance with abstract policy

The consequences of not adhering to the abstract submission policy can vary depending on the specific policies and guidelines established by the conferences. However, here are some potential consequences that may arise**:**

8.1. Disqualification: Failure to comply with the abstract submission policy may result in the disqualification of the abstract from consideration. The abstract may be excluded from the review and selection process, and therefore, the opportunity to present the research findings may be forfeited.

8.2. Exclusion from Presentations: Non-adherence to the policy may lead to exclusion from presenting the abstract at conferences, symposiums, or other academic events. This can prevent residents from sharing their work with a broader audience, receiving feedback, and gaining recognition for their research efforts.

8.3. Program Repercussions: In some cases, non-adherence to program policies, including the abstract submission policy, may result in institutional repercussions. This may

include disciplinary actions.

9. Authorship

The purpose of this policy is to establish clear guidelines and expectations regarding authorship of scholarly work within our residency program. This policy aims to promote fairness, transparency, and accountability in acknowledging and attributing contributions to scholarly activities.

9.1. Definitions

9.1.1. Author: An individual who has made substantial intellectual contributions to the conception, design, execution, analysis, or interpretation of the scholarly work.

9.1.2. Principal Investigator (PI): The individual responsible for the overall direction and management of the scholarly work. In most cases, the PI is the project mentor or the attending faculty member.

9.1.3. Senior author: The primary individual who holds significant responsibility, leadership, and oversight in the research process or case report. In the context of scholarly publications and research endeavors, the senior author is typically an experienced and established contributor, often an attending faculty member or principal investigator.

9.2. To qualify for authorship, individuals must meet the following criteria:

9.2.1. Substantial contributions to the conception or design of the scholarly work, or the acquisition, analysis, or interpretation of data.

9.2.2. Active involvement in drafting and revising the intellectual content of the work.

9.2.3. Final approval of the version to be published or presented.

9.3. Order of Authorship:

9.3.1. The order of authorship should reflect the relative contributions made by each author.

9.3.2. The PI, if applicable, should be identified as the senior or corresponding author.

9.3.3. Determining the authorship order should be based on discussions and consensus among all parties involved, considering their contributions and expertise.

9.4. Responsibilities:

9.4.1. The PI or supervising faculty member has the responsibility to guide and mentor residents in determining authorship and ensuring compliance with this policy.

9.4.2. Residents should maintain accurate records of their contributions to each scholarly work and communicate their roles to the PI and other co-authors.

9.4.3. All authors are responsible for ensuring the accuracy and integrity of the scholarly work and complying with relevant ethical guidelines and policies.

9.5. Dispute Resolution:

9.5.1. In the event of a disagreement regarding authorship, residents should first attempt to resolve the issue by discussing it with the PI or attending faculty and co-authors.

9.5.2. If a resolution cannot be reached, the matter should be escalated to the residency program director or RAPD for further resolution.

9.6. Acknowledgment:

9.6.1. Individuals who do not meet the criteria for authorship but have provided meaningful contributions to the scholarly work should be acknowledged appropriately.

9.6.2. Acknowledgments and authorships must be approved by those recognized before the submission of the abstract.

9.7. Compliance and Review:

9.7.1. Compliance with this policy is mandatory for all residents participating in scholarly activities within the residency program.

9.7.2. This policy will be periodically reviewed and updated as necessary to ensure its continued relevance and effectiveness.

An agreement regarding authorship must be conducted before the abstract is submitted for the consideration of the RAPD and the conference. By adhering to this authorship policy, our residency program aims to foster a culture of integrity, collaboration, and recognition of scholarly contributions among its residents and faculty members.

10. Conference Presentations

The resident is responsible for forwarding the conference letter of acceptance to the Research Associate Program Director (RAPD), Dr. Arelis Febles, and the senior author within one week of receipt. The draft of the corresponding poster or oral presentation must be sent for review at least 10 days prior to the scheduled presentation date. The message should include the conference guidelines for either poster or oral presentations. Residents must ensure that they adhere to the conference guidelines for both poster and oral presentations before submitting the draft for review. It is imperative that residents thoroughly review and adhere to the specific instructions provided by the conference organizers to ensure that their presentations align with the required standards. All posters must be created using the IM Poster Template 2022 PowerPoint template available in the files section of the Microsoft Team for Research – Internal Medicine.

Residents are required to practice poster and oral presentations with the RAPD and designated faculty members to ensure a high level of quality. This requirement is implemented to support

residents in refining their presentation skills, effectively communicating their research findings, and enhancing the overall quality of their presentations. Practices are coordinated by the RAPD after receiving the notification of abstract acceptance.

10.1. Key points regarding this requirement include:

10.1.1. Presentation Skill Development: By practicing oral presentations residents have the opportunity to improve their presentation skills. The RAPD and designated faculty member will provide valuable feedback on aspects such as organization, clarity, delivery, and engagement. This feedback allows residents to refine their presentation style, ensuring that their research is effectively communicated to diverse audiences.

10.1.2. Content Review: The RAPD and designated faculty member can ensure that the research findings are accurately presented, the methodology is clearly explained, and the key messages are effectively conveyed. This review process helps to enhance the accuracy, relevance, and impact of the presentation,

10.1.3. Audience Adaptation: The RAPD and designated faculty member can provide guidance on tailoring the presentation to specific audiences. They can help residents identify and address potential knowledge gaps or areas that require additional clarification. Adapting the presentation to the target audience ensures that the content is understandable and relatable, maximizing the impact of the research.

10.1.4. Presentation Delivery: The RAPD and designated faculty member can provide constructive feedback on the delivery of the presentation, including aspects such as speaking pace, body language, visual aids usage, and overall confidence. By practicing with the research director, residents can develop their presentation delivery skills, ensuring that they engage the audience effectively and convey their research findings with clarity and professionalism.

Practicing oral presentations serves as a quality assurance measure. It helps to identify any areas of improvement, clarify any potential misunderstandings, and ensure that the presentation meets the program's standards for excellence in research communication.

Residents are responsible for adhering to conference presentation requirements when presenting their findings. It is essential for residents to familiarize themselves with the specific guidelines, submission deadlines, and formatting requirements set by the conference organizers.

10.2. Additional points regarding this responsibility include:

10.2.1. Presentation Format: Residents should carefully review the conference's instructions regarding presentation format, such as oral presentation, poster presentation, or e-poster format. They are responsible for preparing their presentation materials in the required format and ensuring that they adhere to any specified guidelines for content, layout, size, and resolution. This includes appropriately citing sources and obtaining necessary permissions for any copyrighted material used in the presentation and obtaining patient consent.

10.2.2. Time Management: Residents must manage their presentation time effectively and stay within the allocated time limits set by the conference. This demonstrates consideration for other presenters and ensures a smooth flow of the program. Practicing the presentation beforehand and timing it accurately can help residents deliver their findings within the assigned time frame.

10.2.3. Professional Conduct: Residents should uphold professional conduct during their conference presentations. This includes dressing appropriately, maintaining a respectful and engaging demeanor, and responding professionally to questions or comments from the audience. They should also be prepared to engage in scholarly discussions, share their research insights, and represent the residency program in a positive and professional manner.

10.2.4. Feedback and Continuous Improvement: Residents should be open to receiving feedback from the conference attendees, organizers, and fellow researchers. They can use this feedback to continuously improve their presentation skills, refine their research findings, and enhance their overall professional development. Engaging in discussions and networking opportunities during the conference can also foster collaborations and future research opportunities.

10.2.5. Networking: Residents should actively participate in conference activities, such as poster sessions, workshops, panel discussions, and conference social events. These provide valuable opportunities to interact with researchers, experts, and peers in their field of study. Active participation demonstrates enthusiasm and a commitment to professional growth. Residents should aim to build and nurture professional relationships during networking opportunities. This includes exchanging contact information, connecting on professional platforms, and following up with individuals of interest after the conference. Maintaining these relationships over time can lead to collaborative research projects, mentorship opportunities, and professional support.

10.2.6. Author listing: The residents are responsible for ensuring consistency with the abstract. By following these guidelines, the residency program ensures that authorship and presentation details remain consistent and transparent:

10.2.6.1. Consistent Author Listing: The author listing and order on posters and slides should mirror that of the abstract. Authors should not be added to a presentation after the abstract has been accepted. Maintaining consistency in authorship ensures clarity and facilitates the identification of the related presentation.

10.2.6.2. Acknowledging Unavailable Authors: If an author is unavailable to work on a presentation after the abstract has been accepted, their name may be removed from the author list. However, their contribution to the study and/or publication should be acknowledged. This ensures transparency and recognition of their involvement in the research.

10.2.6.3. Presenting Author Indication: If an author other than the first-named author is presenting, this should be indicated without altering the author's order. A clear indication of the presenting author allows for proper attribution and acknowledgment during the presentation.

10.2.6.4. Unchanged Presentation Titles: The title of the presentation should not be altered after submission. Therefore, the titles of the abstract and poster or slides should be identical. This maintains consistency and helps conference attendees easily associate the presentation with its corresponding abstract.

By adhering to conference presentation requirements, residents demonstrate their commitment to professionalism, effective communication, and contributing to the scientific community. Following these guidelines helps ensure that their research is effectively shared and that they make a positive impact in their field of study.

11. Adherence to Reporting Guidelines

Following internationally accepted generic reporting guidelines helps to ensure that published articles contain all the information that readers need to assess a study's relevance, methodology, validity of its findings, and generalizability. Research related to the health of humans should have the potential to advance scientific understanding or improve the treatment or prevention of disease. The expectation is that an account of the research will be published, communicating the research results to other interested parties. The publication is generally in the form of articles in scientific journals, which should describe what was done and what was found.

Transparent reporting of health research is of paramount importance for several reasons:

11.1. Reproducibility: Transparent reporting allows other researchers to understand and replicate the study methods, ensuring the reproducibility of research findings. This is crucial for verifying the validity of results and building a solid evidence base for clinical practice.

11.2. Critical Appraisal: Transparent reporting enables readers, including healthcare professionals, policymakers, and patients, to critically evaluate the research methodology, results, and conclusions. This facilitates informed decision-making based on reliable evidence.

11.3. Research Integrity: Transparent reporting helps uphold the integrity of health research. It promotes ethical conduct by ensuring that all aspects of the research, such as participant recruitment, data collection, analysis, and interpretation, are accurately and honestly reported.

11.4. Meta-analyses and Systematic Reviews: Transparent reporting allows for the inclusion of studies in meta-analyses and systematic reviews. These evidence synthesis methods rely on the availability of complete and detailed information to accurately assess the overall impact of interventions or exposures.

11.5. Knowledge Translation: Transparent reporting enhances the translation of research findings into clinical practice. Clear reporting facilitates the implementation of effective interventions and interventions while avoiding potentially harmful or ineffective practices.

11.6. Avoiding Research Waste: Transparent reporting minimizes research waste by ensuring that all relevant information is reported. This prevents duplication of efforts, reduces unnecessary resource consumption, and maximizes the utility of research investments.

11.7. Learning and Improvement: Transparent reporting promotes a culture of continuous learning and improvement in research. By providing comprehensive details about study design, methods, and limitations, researchers can learn from each other's experiences and build upon previous work.

11.8. Ethical Considerations: Transparent reporting fosters ethical considerations in research. By accurately reporting potential conflicts of interest, funding sources, and limitations, researchers demonstrate accountability and maintain public trust in the scientific process.

11.9. Improved Visibility: Reporting guidelines help researchers provide comprehensive and clear descriptions of their study methods, results, and interpretations. This enhances the visibility of the study, making it easier for other researchers to identify and cite the work accurately.

11.10. Enhanced Study Quality: Reporting guidelines promote rigorous and transparent reporting of research, including details about study design, data collection, analysis, and limitations. This improves the overall quality of the study and increases its credibility, which can attract more attention from the scientific community and result in more citations.

11.11. Ease of Evaluation: Reporting guidelines provide a standardized framework for evaluating research studies. This makes it easier for reviewers, editors, and readers to assess the study's quality, relevance, and contribution to the field. Well-reported studies are more likely to be recognized and cited as they undergo a thorough evaluation process.

Various guidelines and reporting standards have been developed, such as the CONSORT (Consolidated Standards of Reporting Trials) statement for clinical trials, STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational studies, and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for systematic reviews and meta-analyses. Many medical journals and scientific meetings require adherence to specific reporting guidelines. The Equator Network library contains a comprehensive, searchable database of reporting guidelines and links to other resources relevant to research reporting.[11]

[1] Guidelines for Reporting Health Research: A User's Manual, First Edition. Edited by David Moher, Douglas G. Altman, Kenneth F. Schulz, Iveta Simera and Elizabeth Wager.

12. Statistic Consultation

Residents within the program are required to consult a statistician during the development of their study proposals and throughout the analysis phase. This policy ensures that residents receive appropriate guidance and expertise in statistical methods, study design, and data analysis to enhance the quality and validity of their research.

12.1. Key elements of this policy include:

12.1.1. Study Proposal Development: Residents are required to involve a statistician from the early stages of study proposal development. The statistician can provide valuable input on research questions, study design, sample size calculations, and statistical analysis plans. Collaboration with a statistician helps ensure that the study is designed with appropriate statistical considerations and addresses potential methodological challenges. Residents should initiate a consultation with a statistician at least four weeks prior to the submission deadline for study proposals. This allows sufficient time for the statistician to review the research objectives, study design, and provide feedback on the statistical considerations of the proposal.

12.1.2. Statistical Analysis Planning: Residents are required to consult with a statistician to develop a comprehensive statistical analysis plan. The plan outlines the statistical methods to be used for data analysis, including descriptive statistics, inferential tests, regression models, or other relevant analytical techniques. The statistician assists residents in selecting appropriate statistical tests, interpreting the results, and addressing any statistical considerations specific to the study design. Residents should engage with the statistician for statistical analysis planning at least four weeks prior to the anticipated start of data analysis. This early involvement ensures that the statistical analysis plan is well-defined, addressing key research questions and employing appropriate statistical methods.

12.1.3. Data Management and Quality Assurance: Residents receive guidance from the statistician on data management procedures, including data collection, storage, cleaning, and quality assurance. The statistician ensures that data are collected and managed in a manner that facilitates accurate and reliable statistical analysis. Residents should provide the necessary data to the statistician within two weeks of data collection completion. This allows the statistician ample time to conduct data cleaning, exploratory analyses, and perform the agreed-upon statistical analyses within the designated timeframe.

12.1.4. Results Interpretation and Reporting: Residents should schedule a follow-up consultation with the statistician once the analysis is completed. This should occur at least two weeks before the deadline for result interpretation and reporting. The meeting provides an opportunity to discuss the findings, their statistical implications, and clarify any questions regarding data interpretation.

12.1.5. Collaboration and Communication: Residents are expected to maintain regular communication with the statistician throughout the research process. Collaboration with the statistician facilitates discussions on statistical methodology, data interpretation, and any necessary adjustments to the analysis plan based on emerging findings.

It is the responsibility of residents to proactively reach out to the statistician and schedule the necessary consultations within the specified time frames. Adhering to these deadlines ensures that residents receive timely and comprehensive statistical support, promotes efficient research progress, and facilitates the timely completion of data analysis and reporting.

Residents should be aware that these deadlines are subject to adjustment based on the specific requirements of each research project and the availability of the statistician. It is essential to communicate and collaborate with the statistician effectively to meet the established deadlines and maintain a productive working relationship throughout the research process.

13. IRB Application and Approval

The residency follows the policies and procedures for research as outlined by the Office for Human Research Protections (OHRP). This includes the requirement of Institutional Review Board (IRB) approval, whether for full, expedited, or exempt status, for those studies that meet the definition of human research. Although projects that only involve secondary data analysis do not involve interactions or interventions with humans, they may still require IRB review, because the definition of "human subject" at 45 CFR 46.102(f) includes living individuals *about whom an investigator obtains identifiable private information for research purposes*.

13.1. Key elements of this policy include:

13.1.1. Study Eligibility: Before submitting an IRB application, the investigators are responsible for determining if an IRB review is required for your project.

13.1.2. IRB Status: Proof of IRB approval is a mandatory requirement for study implementation and publication.

13.1.3. Disclosure of IRB protocol number: All dissemination materials must include the number of the approved IRB protocol or disclosure of exempt status.

13.1.4. Up-to-Date Human Research Training: Residents are responsible for maintaining up-to-date human research training certifications. This involves completing any required courses or modules related to human subjects' protection, ethical conduct in research, and regulatory compliance. By staying current with training requirements, residents ensure they have the necessary knowledge and skills to conduct research responsibly.

13.1.5. Study Protocol Closure: Residents are responsible for appropriately closing study protocols once data analysis and all research activities are completed. This includes finalizing data collection, ensuring proper documentation of all study procedures, and notifying the relevant parties (such as the RAPD, IRB, or sponsoring institution) that the study has concluded.

13.1.6. Continuing Reviews: If a study requires ongoing review by the IRB, residents are responsible for submitting the necessary documentation and updates to continue the review process on time. This includes providing progress reports, modifications to

study protocols, and any other requested information. By fulfilling this responsibility, residents help ensure that the study remains in compliance with ethical and regulatory requirements throughout its duration.

13.1.7. Reporting Adverse Events: In cases where adverse events or unexpected outcomes occur during the course of the research, residents have a responsibility to promptly report these events to the appropriate authorities, such as the IRB or relevant oversight committees. Reporting adverse events is crucial for maintaining participant safety, evaluating study risks and benefits, and ensuring transparency in the research process.

By actively fulfilling these responsibilities, residents contribute to the ethical and responsible conduct of research within the residency program. They demonstrate a commitment to maintaining the highest standards of participant protection, compliance with regulations, and the overall integrity of the research conducted.

14. Academic Integrity

Honesty and responsibility are pillars of research. The program expects that all residents will abide by the Students' Bylaws of the University of Puerto Rico (November 3, 2011). Chapter VI: Disciplinary Norms and Procedures, Part B, Article 6.2, defines academic dishonesty.

14.1. Examples of academic dishonesty include the following:

14.1.1. Plagiarism: Plagiarism refers to the act of using another's ideas, words, or work without giving appropriate credit or acknowledgment. It involves presenting another person's intellectual property as one's own, whether it is a written document, research findings, artwork, computer code, or any other form of creative expression. Plagiarism is considered a serious ethical violation and academic misconduct, as it undermines the principles of intellectual honesty, integrity, and originality. To avoid plagiarism, it is important to properly cite and attribute all sources used in academic or scholarly work, giving credit to the original authors or creators.

14.1.2. Fabrication: Involves the intentional creation or invention of data, results, or findings that did not actually occur during the research process.

14.1.3. Falsification: Refers to the manipulation or alteration of research data, methods, or processes in a way that distorts or misrepresents the actual findings or outcomes.

14.1.4. Conflict of Interest: Non-disclosure of potential conflicts of interest that may influence research, such as financial or personal relationships that could compromise objectivity.

14.1.5. Non-compliance with Legal and Regulatory Requirements: Failure to adhere to applicable laws, regulations, and ethical guidelines that govern research conduct, data handling, participant protection, and other related aspects. Non-compliance can take various forms, such as:

14.1.5.1. Failure to obtain necessary approvals: Researchers may fail to obtain

required permissions, licenses, or clearances from relevant regulatory bodies or institutional review boards (IRBs) before initiating research involving human subjects, animals, or sensitive data.

14.1.5.2. Violation of privacy and data protection regulations: Researchers may mishandle or misuse sensitive data, infringe on privacy rights, or fail to comply with regulations regarding the collection, storage, processing, or sharing of personal or sensitive information.

14.1.5.3. Breach of ethical guidelines: Researchers may deviate from ethical principles and guidelines, such as obtaining informed consent, ensuring confidentiality, minimizing harm to participants, or maintaining the welfare of animal subjects.

14.1.5.4. Non-adherence to financial regulations: Researchers may fail to comply with financial regulations, such as accurately reporting funding sources, disclosing conflicts of interest, or misusing grant funds.

Non-compliance with legal and regulatory requirements in research can have serious consequences, including reputational damage, legal repercussions, loss of funding, publication retractions, and harm to research participants. To maintain research integrity, it is crucial for researchers and institutions to be aware of and abide by relevant laws, regulations, and ethical guidelines, seek necessary approvals, and follow best practices in research conduct and data handling.

14.2. Article 6.4 establishes the sanctions that will be applied. Sanctions may include:

14.2.1. Written warning.

14.2.2. Probation for a defined period during which any further violation of any rule will result in suspension or separation. Probation may include the imposition of conditions that limit the use of facilities, resources, or privileges.

14.2.3. Suspension from the University for a defined period. Violating the terms of the suspension will result in an extended suspension or permanent expulsion from the University.

14.2.4. Permanent expulsion from the University of Puerto Rico.

14.2.5. Acts that constitute violations of this Regulation and damage property may also require compensating the University or the affected individuals for the expenses incurred in repairing the damages.

14.2.6. Assignment of work within the university community.

15. Research Misconduct Process

In cases of research dishonesty or misconduct, a series of steps and consequences are implemented

to address the situation and maintain the integrity of the research environment.

15.1. Investigation and Inquiry: Upon the discovery or receipt of allegations of research dishonesty or misconduct, an investigation or inquiry will be initiated by the RAPD. This process aims to gather evidence, interview involved parties, and evaluate the extent and nature of the misconduct.

15.2. Referral to Residency Program Director: If research misconduct is apparent, the case will be referred to the Program Director. This referral serves to inform the Program Director about the misconduct and can result in further investigation or disciplinary actions within the context of the residency program. The Program Director may initiate an internal review or disciplinary process specific to the residency program. This can involve assessing the impact of the misconduct on the individual's progression in the program, determining appropriate remedial measures, or deciding on further disciplinary actions within the program's framework.

15.3. Corrective Actions: If research misconduct is confirmed, corrective actions will be taken to address the situation. These actions may include the retraction of published abstracts or papers, the correction of erroneous data or conclusions, and revisions to research protocols or reports.

15.4. Institutional Sanctions: As previously established, the Bylaws of the University of Puerto Rico (November 3, 2011). Chapter VI: Disciplinary Norms and Procedures, Part B, Article 6.3, lists possible disciplinary actions, including formal warnings, suspension, or expulsion from the residency.

15.5. Legal and Regulatory Consequences: In cases of severe research misconduct, legal and regulatory consequences may arise. This can include civil lawsuits, criminal charges, fines, and penalties imposed by regulatory bodies or government agencies.

16. Summary of Program Deadlines

Residents should be mindful of program deadlines and ensure timely submission of required materials to facilitate smooth and organized conference preparations.

RESEARCH POLICY AND PROCEDURE MANUAL – DEADLINES

Procedures	Reviewer/Recipient	Deadline (Calendar days/weeks)
Abstract Review – Send abstract for review and approval	Research Assistant Program Director Designated Faculty Member Senior author (Attending Faculty or Principal Investigator)	10 days prior to the anticipated date of submission
Abstract Review Notification	Primary Author	7 days after receipt

Procedures	Reviewer/Recipient	Deadline (Calendar days/weeks)
	Program Director Designated Faculty Member Senior author (Attending Faculty or Principal Investigator)	
Abstract Acceptance Letter or Notification – Send abstract acceptance letter	Research Assistant Program Director Residency Administrator Residency Coordinator	7 days after receipt of the letter
Travel Approval - Submit a travel request detailing the proposed trip's purpose, dates, and destination	Chief of Residents Program Director Residency Administrator	2 weeks after abstract acceptance
Travel Expenses/Reimbursement - Submit a travel request and the necessary supporting documentation	Residency Coordinator	20 days prior date of travel
Poster/Oral Presentation Draft Review – Send presentation for review and approval	Research Assistant Program Director Designated Faculty Reviewer Senior author (Attending Faculty or Principal Investigator)	10 days prior to the date of travel
Abstract Review Notification	Primary Author Program Director Designated Faculty Member Senior author (Attending Faculty or Principal Investigator)	7 days after receipt
Poster/Oral Presentation Draft with Changes (if Applicable)	Research Assistant Program Director Designated Faculty Reviewer Senior author (Attending Faculty or Principal Investigator)	2 day after receipt of the reviewed draft
Statistical Consultation	Statistician Research Assistant Program Director	4 weeks prior (Study proposal & statistical planning) 2 weeks prior (Data

Procedures	Reviewer/Recipient	Deadline (Calendar days/weeks)
	Senior author (Attending Faculty or Principal Investigator)	management & analysis)

APPENDIX 1

HOSPITAL UNIVERSITARIO
CENTRO MEDICO DE PUERTO RICO

AUTORIZACION PARA DIVULGACION DE INFORMACION, TOMAR FOTOGRAFIAS, PELICULAS, ENTREVISTAS O GRABACION

Yo _____, mayor de edad autorizo a la Administración del Hospital Universitario y a mi médico de cabecera a:

_____ a. Tomar fotografías o películas de mi persona para propósitos:

_____1. educativos
_____2. de interés a la comunidad
_____3. legales

_____ b. Que se le tomen fotografías a mi _____, _____
(Parentesco) (Nombre

_____, admitido-a en _____
del Paciente) (Departamento)

Hab. # _____, con propósito: _____.

_____ c. Que se me entreviste por los representantes de _____ con propósitos:

_____1. educativos
_____2. de interés a la comunidad
_____3. legales
_____4. Otros, _____
(Especifique)

_____ d. Conceder una grabación mía con los representantes de _____
_____, con propósitos:

_____1. educativos
_____2. de interés a la comunidad
_____3. legales
_____4. Otros, _____
(Especifique)

_____ e. Divulgar información relativa a mi condición médica con propósitos:

_____1. educativos
_____2. de interés a la comunidad
_____3. legales
_____4. Otros, _____
(Especifique)

_____ _____
Firma paciente o familiar Fecha

_____ _____
Firma persona autorizada Fecha

_____ _____
Firma Director Ejecutivo o Representante Fecha

Revisado: Agosto 2010