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Compliance with research standards within gynecologic oncology fellowship: A Gynecologic Oncology Fellowship Research Network (GOFRN) study☆

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HIGHLIGHTS

- Gynecologic oncology fellow non-compliance with research standards is high.
- Areas of non-adherence include authorship assignment and non-secure data storage.
- Pressure from senior authors and lack of support may predispose to non-adherence.
- Barriers to non-adherence should be addressed.

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ABSTRACT

Objectives. Participation in clinical and basic science research is emphasized in gynecologic oncology training. We sought to identify trends in adherence to expected research practices and reasons for non-adherence among gynecologic oncology fellows.

Methods. An anonymous 31-question online survey assessing academic behaviors, including IRB compliance, authorship assignment, data sharing, and potential barriers to non-adherence was distributed to all SGO gynecologic oncology fellow members in July 2016. Descriptive statistics and univariate analyses were performed.

Results. Of 190 members, 35.3% (n = 67) responded. 73% (n = 49) of respondents reported personal non-compliance and 79.1% (n = 53) reported having witnessed others being non-complaint with at least one expected research practice. Areas of compliance failure included changing a research question without appropriate IRB amendment (20%; n = 14), conducting research under a nonspecific IRB (13.9%; n = 9), and performing research without IRB approval (6.1%; n = 4). Longer institutional time for IRB approval was significantly associated with IRB non-adherence ($p < 0.05$). First year fellows were more likely to use a nonspecific IRB ($p = 0.04$) or expand a question without amending the IRB ($p = 0.04$). When asked about storage of protected health information (PHI) for research, 53% reported non-secure storage with 17.1% (n = 6) having done so for >1000 patients. Thirty respondents (45.5%) assigned authorship to someone who failed to meet ICMJE criteria and twelve (18.5%) accepted authorship without meeting ICMJE criteria. Most commonly cited reasons for non-adherence were: cumbersome IRB processes (80.3%), pressure from senior authors (78.8%), fear of someone else publishing first, (74.2%) and lack of support navigating appropriate research practices (71.2%).

Conclusions. Fellow non-compliance with expected research practices is high, particularly with regards to secure storage of PHI and appropriate authorship assignment. Time-consuming and cumbersome IRB procedures, perceived pressure from senior authors, and lack of research support contribute to non-adherence. Further support and education of gynecologic oncology fellows is needed in order to help address these barriers.

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1. Introduction

The forward momentum of science is dependent upon valid and reproducible findings published in the scientific literature. Over the last two decades, reports of scientific misconduct have led to an increasing number of articles retracted from major journals [1–6]. Adherence to all expected research practices, particularly in an educational environment, is a critical component of academic integrity.

Increasing awareness of both intentional and unintentional scientific misconduct has led to the creation of various organizations, including the Office of Research Integrity founded in 1992, designed to promote research integrity and prevent scientific misconduct [7]. Guidelines, institutional review boards, and criteria for authorship and publication can help authors steer clear of mishaps. However, as rules and regulations become more complicated to navigate, real and perceived non-compliance are important to evaluate. Studies investigating scientific misconduct have found that while the most serious types of misconduct are rare, non-adherence to expected research standards is common [8]. As the organizational and legal environments become more stringent, physician-scientists must ensure that, not only are they aware of and compliant with evolving guidelines and ethical practices, but that they are teaching and modeling compliance for trainees.

Gynecologic oncology fellowships are designed to engage trainees in research. Accredited programs require 1–2 years of dedicated research time [9]. Pressures to become academically productive may lead to lapses in adherence as early as the fellowship application process. Frumovitz et al. reported that as many as 17% of publications that were cited on gynecologic oncology fellowship applications could not be verified [10]. Evidence of these violations even prior to fellowship training, make it more critical that adherence to expected research and ethical practices are emphasized.

At present, there is a lack of information regarding adherence to professional values and practices in an academic gynecologic oncology research environment. It is critical that we embrace a training culture that promotes academic integrity and yields physicians capable of conducting high quality research compliant with expected research standards. The objective of our study was to identify trends in perceived adherence to standard professional research practices among gynecologic oncology fellows and to determine barriers that may contribute to lapses in expected research practices.

2. Methods

2.1. Study design

We designed an anonymous electronic questionnaire that assessed academic behaviors, including IRB compliance, authorship assignment, data sharing, and potential barriers to non-adherence. The study was approved by the Institutional review board (IRB) at Cleveland Clinic Foundation and by the Society of Gynecologic Oncology for the purpose of surveying fellow members. The survey was pilot tested by four gynecologic oncology fellows-in training for feedback.

2.2. Survey creation and variables

The survey consisted of 31 questions designed to assess fellow demographics, institutional research resources, IRB protocol compliance, authorship assignment, data storage practices and reasons for non-adherence to expected guidelines. The first part of the survey queried gender, year of fellowship training, geographical training region, planned future practice setting (academic, private practice or combination) and number of peer reviewed articles published as both a first author and co-author within the last 12 months of training.

The second part of the survey assessed institutional resources by querying time for IRB processing, access to allocated research staff (including research managers, coordinators or nurses) to help in navigating the research process, the presence of dedicated statistician available to fellows or programs/registries, and access to secure data collection, storage and sharing (including RedCAP). This was followed by a series of questions to determine adherence to IRB protocols during fellowship. These questions focused on expected IRB practices including performing research without IRB approval or under a generalized "umbrella" IRB, changing the research question without amending the IRB, retroactively writing an IRB after performing the research, and presenting research at national meetings or publishing research in a peer-reviewed journal without IRB approval. Respondents were requested to respond with "Yes", "No" or "No, but I have witnessed others in our field do this." Additional questions asked if participants had ever falsified data or had used another's ideas for research without permission or giving credit. If positive responses were received, reasoning for this behavior was requested.

Fellows were queried regarding non-secure storage of protected health information (including on non-secured laptop, personal email accounts and non-secure web sharing programs) and data sharing with other institutions prior to the appropriate data sharing approval. Respondents who answered affirmatively to non-secure storage of PHI were asked to report the number of patient files stored. To determine compliance with defined authorship criteria, fellows were asked if they had ever assigned authorship to someone not meeting the International Committee of Medical Journal Editors (ICMJE) criteria or had accepted authorship when they did not meet these criteria. Affirmative answers were followed with an additional question to determine the reason(s) for this authorship assignment [11].

The final portion of this survey assessed fellows' interpretation of how certain variables may influence overall non-adherence with research practices. Fellows were asked if pressure from senior authors, lack of research support, inability to comply due to training hours restrictions, cumbersome processes, confusion with practices, and fear of others publishing first significantly contributed to non-adherence. The complete survey has been included in Appendix A.

2.3. Study participants

An email invitation to participate in the anonymous study was sent directly from the Society of Gynecologic Oncology (SGO) and distributed to all fellow members of the society in June and July of 2016. Within the body of the email, fellows were invited to participate in the confidential survey via the RedCAP website on a voluntary basis with an "opt-out" option [12]. In order to incentivize participation, respondents were given the chance to be entered into a raffle to win one of two $50 Amazon gift cards. Members were sent two subsequent email invitations to participate in 1–2 week intervals with completion of recruitment on July 21st 2016. No identifying data was collected, including the respondent's fellowship institution. Secure data storage was maintained with REDCap software [12]. All fellows who were emailed the survey were included in the denominator of total surveys to calculate the response rate.

2.4. Statistical analysis

All returned surveys, including those with incomplete responses, were used for the final analysis. Descriptive statistics were performed to assess fellow demographics and for all survey responses. Fellow survey responses were analyzed with for multiple co-variates using Fisher's exact test and Chi Square tests. Selected co-variates used to compare survey responses included year of training, geographical location, gender, future practice setting, number of publications, institutional resources and IRB processing time. Two-tailed p-values < 0.05 were considered significant. Statistical analysis was performed with JMP software (12.2.0).

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