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Understanding Conflict of Interest for Academic Entrepreneurs

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Summary

- A conflict of interest (COI) is defined as the presence of a risk for an undue influence on primary goals due to a secondary goal such as financial gain. Individuals must understand that the mere presence of the risk, and not the actual occurrence of the undue influence, constitutes a potential COI.
- In biomedical research, COI policies protect human subjects and research integrity while preserving public trust. Damage caused by actual research misconduct is severe and creates wide and long-lasting public mistrust. Thus, individuals should not view COI policies as burdensome and instead should consider them as preventative strategies that protect them from broader repercussions after a concern for research bias has been raised.
- The disclosure of individual financial relationships is a critical but limited first step in the process of identifying and managing COIs.
- The presence and severity of a COI in an individual's disclosure are assessed by the institution's COI committee to determine appropriate strategies for the management of the COI, such as the need for more specific disclosure information, restriction of the individual's role in the research, or even, in some circumstances, the elimination of a conflicting relationship.

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Understanding Conflict of Interest for Academic Entrepreneurs

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Topic Relevance by Timeline

Summary

- A conflict of interest (COI) is defined as the presence of a risk for an undue influence on primary goals due to a secondary goal such as financial gain. Individuals must understand that the mere presence of the risk, and not the actual occurrence of the undue influence, constitutes a potential COI.
- In biomedical research, COI policies protect human subjects and research integrity while preserving public trust. Damage caused by actual research misconduct is severe and creates wide and long-lasting public mistrust. Thus, individuals should not view COI policies as burdensome and instead should consider them as preventative strategies that protect them from broader repercussions after a concern for research bias has been raised.
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- Although some of the COI disclosure requirements are standard across medical institutions, COI policies among institutions and professional organizations vary. Therefore, individuals must familiarize themselves with their respective institutions' policies and procedures for the identification and management of COIs.
- Physician-scientists who are directly involved in patient care, medical education, or clinical practice guideline development must exercise additional caution to disclose and manage potential COIs.

Introduction

Research collaborations between academia and industry are essential for rapid discovery and development of new drugs and medical devices to improve individual and public health (Moses et al.). Meanwhile, patients, physicians, and policymakers must be able to trust that the integrity of the design, conduct, and reporting of research born out of such collaborations are not compromised by any potential undue influence of financial interests on professional judgement. COI policies aim to protect human subjects and research integrity, and thereby preserve public trust, while fostering the scientific benefits that arise from financial relationships between academics and industry.

This chapter aims to provide academic entrepreneurs and academic researchers partnering with industry a concise review of the guidelines for the identification and management of COIs. We address two central elements of COI that are of importance to the academic entrepreneur—namely, COIs faced by biomedical researchers and COIs that are specific to physician-scientists due to their direct involvement with patients. A better understanding of the nature of COIs and the purpose of COI policies enables researchers and physicians to concentrate on their primary goals by being better prepared and therefore more confident in navigating potential COI issues. Additionally, knowledge of the individual's institutional COI policy would prepare the academician to plan the logistics needed to manage a COI and appropriately allocate resources to successfully execute the research study. For example, if an individual is offered equity and the institution's COI policy prohibits the individual from participating in the related research, the individual could plan to have a co-investigator perform the research study and allocate funding for the co-investigator in advance. Earlier consultation with the institution's COI committee allows them to explore the situation and gives opportunity for creative solutions to mitigate the risk of bias. A COI is best managed when the academic/researcher is an active partner of the institution's COI committee.

Definition and Risks Associated with Conflicts of Interest in Biomedical Research and Clinical Care

The goals of academic medicine are to deliver safe, effective healthcare and to conduct research that will lead to improvements in care, based on critical appraisal of research. The goal of the for-

profit medical industry is to make financial gains by developing, marketing, and selling treatments and services that seek to improve the health of patients (Cappola and FitzGerald). The Bayh-Dole Act of 1980 encourages academic universities to partner with the industry. Benefits include increased opportunity to access data, equipment, and materials, and to foster the translation of basic research into widely available commercial products. However, when the goals of academic medicine and medical companies merge as a result of collaboration between the two, it creates circumstances where the financial goals of the industry may adversely affect the primary goals of academic medicine—thus creating a conflict of interest (Pizzo et al.). Studies have shown that industry-sponsored research is less likely to be published than research sponsored by other institutions or individuals; it is also more likely to show a favorable result toward the company's product, even though the methodological quality is as good or better than non-industry-sponsored research studies (Lexchin et al.; Lundh et al.). Even in the absence of evidence of actual bias, there is often a public perception that financial interests threaten academic and clinical judgment (Besley et al.; Kesselheim et al.). This is exacerbated by well-publicized stories in the media regarding conflicts of interest in medicine and medical research, which have further undermined the public's trust in researchers and research institutions.

Conflicts of interest are defined as circumstances that create a risk for professional judgments or actions regarding a primary interest to be unduly influenced by, or perceived to be influenced by, a secondary interest. The presence of risk of undue influence—and not the actual occurrence—defines a COI. Timely identification and management of a COI to avoid any real or perceived bias in the design, conduct, or reporting of research, and in the care of patients and research subjects, are the ultimate goals of COI policies.

The three key elements of a COI are:

1. *Primary interest*: Promoting and protecting the integrity of research, the quality of medical education, and the welfare of patients are the primary interests. Researchers and physicians exercise their professional judgment to ensure that the primary interests are met. Patients, research participants, medical trainees, and the public at large trust that the primary interests are the top priority for researchers and physicians.
2. *Secondary interest*: Financial interests are the most common type of secondary interest and are relatively more objective and quantifiable. Other secondary interests include the desire for recognition and professional advancement, and the desire to favor friends, family, students, or colleagues. The presence of a secondary interest that may cause a real or perceived undue influence on a primary interest constitutes a COI.
3. *Conflict of interest*: It is not only the actual occurrence of a compromised primary interest that constitutes a COI but also the likelihood or the perception that professional judgment could be unduly influenced by a secondary interest under certain circumstances or relationships, and the gravity of the damage that could result.

Significant financial interest (SFI) and financial conflict of interest (FCOI) are two frequently used terms in relation to an individual's COI. These terms are defined by federal Public Health Service (PHS) regulations and frequently adopted to apply to all COI analysis via institutional policies.

An SFI is an interest in an outside entity as a result of which the individual receives or holds the potential to receive financial benefit. An SFI must be disclosed to the institution by the researcher. The thresholds for an SFI are defined. However, an SFI does not automatically create an FCOI. The threshold for what may constitute an FCOI can be and often is determined by institutional policy or practice. In general, an SFI exists if:

- The value of any remuneration received from any publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceed \$5,000. Remuneration includes salary, consulting fees, honoraria, or paid authorship; equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.
- The value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or *any* equity interest that is held by the investigator or the investigator's spouse or dependent children, regardless of monetary value.
- The investigator holds any intellectual property rights and interests such as patents or copyrights upon receipt of any income related to such rights and interests (see the chapter "Intellectual Property: Ownership and Protection in a University Setting").

A FCOI is present when an SFI could directly and significantly affect the design, conduct, or reporting of scientific research.

COI for the academic entrepreneur consists of three segments: research COI, clinical care COI, and commitment COI. Research COI refers to financial or personal situations that may compromise the conduct or reporting of research. Clinical care COI refers to situations where a treating physician or health professional's COI may affect clinical care of the patient. Finally, commitment COI refers to situations where associations with outside business entities may negatively impact the individual's ability to meet primary responsibilities to the institution. Conflict of commitment generally includes the use of an individual's time that is meant for institutional responsibilities, more than minimal use of institutional resources to support personal activities, and fiduciary duty to an outside entity. Use of institutional resources includes use of office or laboratory space, secretarial services, and graduate students to work on projects related to the individual's outside interests. A fiduciary duty to an outside entity that conflicts with one's obligations to their primary institution can also be problematic.

COI policies aim to maintain the integrity of professional judgment and sustain public confidence in professional judgment. While some physicians and researchers may believe that actual occurrences of COI are rare and COI policies are unnecessarily burdensome, one must understand that

COI policies are preventative strategies (Rosenbaum, “Reconnecting the Dots—Reinterpreting Industry–Physician Relations”; Rosenbaum, “Beyond Moral Outrage — Weighing the Trade-Offs of COI Regulation”; Rosenbaum, “Conflicts of Interest”). By adhering to COI policies, researchers can avoid more serious repercussions. A researcher’s conflict of interest can easily lead to mistrust that might affect the researcher, colleagues, the reputation of the institution, and potentially its ability to conduct future research. It is the responsibility of the research community to assure the public that the integrity of researchers’ professional judgments is not compromised by any external financial relationships or other personal interests they may have.

Disclosure of Interests to the Institution

The first step to identify a potential COI is reporting to the institution all individual financial relationships and/or other outside interests that may relate to institutional responsibilities, such as research and clinical care. The institution’s COI committee then assesses and acts upon the disclosed information, which may include: a need for more specific disclosure information or obligations to disclose the conflicting interests, some restriction of the individual’s role in the research, or even the elimination of a conflicting interest or relationship. Institutions vary in disclosure requirements under their policies, and therefore individuals must familiarize themselves with the respective institutional policies (often available through the institution’s technology transfer or sponsored research offices) (see the chapter “Working with the University Technology Transfer Office”). In addition, the requirements of federal funding agencies or other research sponsors impact the institutional policies. Table 1 lists examples of what might constitute a financial conflict of interest subject to disclosure. Some of the common disclosure requirements are as follows:

- Disclosure requirements are applicable to all research investigators regardless of title, position, or whether the financial reward was directly received.
- The investigator must disclose their own SFI along with those of their spouse and dependent children.
- Any SFI that reasonably appears to be related to the investigator’s institutional responsibilities must be disclosed. Examples include financial interests that arise from extramural activities that derive from the investigator’s professional standing or are within that investigator’s expertise in their professional field(s) of discipline, and equity in or serving in a fiduciary role for an outside organization if that organization conducts or seeks to conduct business related to the investigator’s field of discipline.
- Generally, institutions require that investigators report these interests for the prior 12 months.
- Any newly discovered or acquired SFI must be updated within a specified duration (30 days commonly) and annually.
- Investigators must receive COI training prior to participating in PHS-funded research and every four years thereafter, or whenever there is a material change to the PHS regulations or the institution’s COI policy.

Table 1. List of Interests to Disclose to Institution.

Research grants and contracts
Consulting agreements
Participation in speakers bureaus
Honoraria for speaking at other academic institutions
Intellectual property, including patents, royalties, licensing fees
Stock, options, warrants, and other ownership (excepting general mutual funds)
Position with a company
Company governing boards
Technical advisory committees, scientific advisory boards, and marketing panels
Company employee or officer, full or part time
Authorship of publications prepared by others
Expert witness for a plaintiff or a defendant
Other payments or financial relationships

Assessment of a COI

The second step is the assessment of a COI by the institution and/or its COI committee. Several factors determine the scrutiny of review and the severity of the potential conflict. Institutions may vary in the specific thresholds they use. Key among these are the likelihood of bias or the perception of bias, and the potential for harm to human subjects and/or risk to the integrity of the research or decisions regarding clinical care.

The likelihood of bias is generally assessed by considering the following factors:

- Value of secondary interest: The greater the potential for financial gain, the greater the risk of undue influence. For example, equity or other ownership in a company may pose a higher risk of a COI. However, even smaller-value secondary interests, such as advisory fees to researchers, may constitute a COI, depending on the magnitude of the financial interest.
- Scope of relationship: The duration and depth of the relationship affects the likelihood of undue influence. Longer and closer relationships such as multiyear consulting agreements, leadership roles in a company board, or serving on a company's scientific advisory board may have greater potential for a COI.
- Extent of discretion: The potential impact of undue influence increases with the degree of involvement of the individual in the particular project. For example, a principal investigator (PI) has ultimate responsibility for all aspects of the research study and thus, in comparison

to other study team members, presents a greater risk of affecting the design, conduct, or reporting of the research.

- **Extent of accountability:** The institutional tolerance and culture determine the accountability of an individual. The lesser the accountability of the individual to the institution, the greater the risk from a COI. For example, when the sanctions for policy violations are more severe, accountability is greater and therefore there may be a lower risk of occurrence of undue influence.

The severity of potential harm is determined by:

- **Nature of the research:** The degree of potential harm depends in part on the nature of the research, and whether it is bench research, animal research, human observational studies, or clinical research. In general, clinical trials involving human subjects pose greater risk of potential harm than bench or animal research.
- **Number and nature of those affected:** The greater the scope of potential consequences, the greater the potential impact of a COI. For example, clinical practice guidelines have a wider range of influence and affect a greater number of patients. Similarly, if the results of a research study are likely to have a direct impact on the standard of care for a particular disease, the potential impact of a COI is likely to be greater.

Strategies for Managing COIs in Research

The severity of a COI as assessed by the institution and/or its COI committee informs the specifics of the management strategies (see Figure 1 at the end of the chapter). The goals of COI management are to sustain the scientifically beneficial collaboration between the academician and outside industry while preventing any actual or perceived undue influence or bias that may affect the integrity of decision-making in clinical care or research (see the chapter “Forming and Maintaining Meaningful Partnerships Between Academic Scientists and Corporations”).

Reporting on SFIs to the institution is generally required prior to the start of the study. Once a COI is identified, it is generally managed by disclosure of the interest to potentially affected parties (e.g., other members of the research team, human subjects or patients, the scientific community, and the general public) at a minimum, and then, in many circumstances, by one or more of the following management strategies: reducing financial interests, restricting or prohibiting the individual’s role in the research activity, or providing oversight of the research by a non-conflicted party. An example of a reduction of a financial interest is the reduction in the value of the financial relationship so that it falls below a given threshold level established by the institution. Examples of a restriction of an individual’s role include modifying the design of the research project, having an investigator with no conflict of interest to serve as the principal investigator, limiting the participation of the investigator (e.g., no participation in recruiting or consenting), and requiring independent review of some aspects of the research (commonly, data analysis).

Individuals generally are not permitted to serve as principal investigators on clinical trials/interventional studies if they have an FCOI with respect to the research. However, in some situations, restricting an individual's role may not be possible or may be unsafe, and exceptions are made in such situations. For example, a surgeon who holds a patent on a new implantable device may be the only surgeon with the expertise necessary for the safe implantation of the device. In this case, the COI committee may make an exception and allow the surgeon to participate in the clinical trial. However, the committee will also establish an effective mechanism to protect the safety of the research subjects and the integrity of research by employing a combination of management strategies that could include: restrictions on the PI's role in the recruitment and consenting of study subjects; use of internal and/or external data safety monitoring boards; independent review or oversight of the analysis of study data; disclosure of the COI to subjects and members of the study team, and in publications and presentations; regularly auditing the informed consent and research subject enrollment process; and involving a patient representative during the consent and research enrollment process (Bero; Brennan et al.; Pizzo et al.).

In addition to the individual's institution, other organizations such as the United States Congress, the Food and Drug Administration (FDA), and the International Committee of Medical Journal Editors (ICMJE) also ensure that standards of research methodology, analyses, and reporting are maintained. Principal investigators of clinical trials must register and report details of the research protocol, primary and secondary endpoints, and methods of analysis of clinical trials on clinicaltrials.gov. Any departure from the protocol is thus easily detectable to the public, and the public is also able to check whether or not trial results have been published. Additionally, the ICMJE requires authors to use the CONSORT checklist for reporting the results of clinical trials, and the FDA requires statisticians who are independent of the clinical investigators and trial-sponsoring medical companies to prepare statistical reports for data monitoring (*Consort - Welcome to the CONSORT Website; ICMJE | Recommendations | Preparing for Submission*).

Prohibition or Elimination of COIs in Research

In some instances, prohibition or elimination of the conflicting interest is the only way to effectively manage the potential conflict of interest. When the risks of a financial relationship or other conflicting interest significantly outweigh any potential benefits from the relationship, or the severity of the conflict is high enough that it jeopardizes the integrity of the research significantly, institutional COI policies can completely prohibit or eliminate such relationships. A COI may be eliminated by requiring the individual to sell any company stock they own, resign from a company's advisory board, or terminate any consulting work for the company. Alternatively, the individual may forgo participation in the research activity and continue to maintain the financial relationship.

As mentioned earlier, management of COIs varies between institutions. This is of particular importance to academic entrepreneurs who may be looking to transfer to another institution. One

should not assume that COI policies would be the same at the new institution. For example, the institution the academic entrepreneur may want to transfer to may have stricter COI policies, and the individual may be required to give up intellectual property or equity (see the chapter “Intellectual Property: Ownership and Protection in a University Setting”). It is therefore important that the researcher understand the COI policies of the new institution prior to the transfer. A meeting with the technology transfer office at the new institution during the interview process and a review of possible COIs based on the new institution’s policy are often helpful in this regard (see the chapter “Working with the University Technology Transfer Office”).

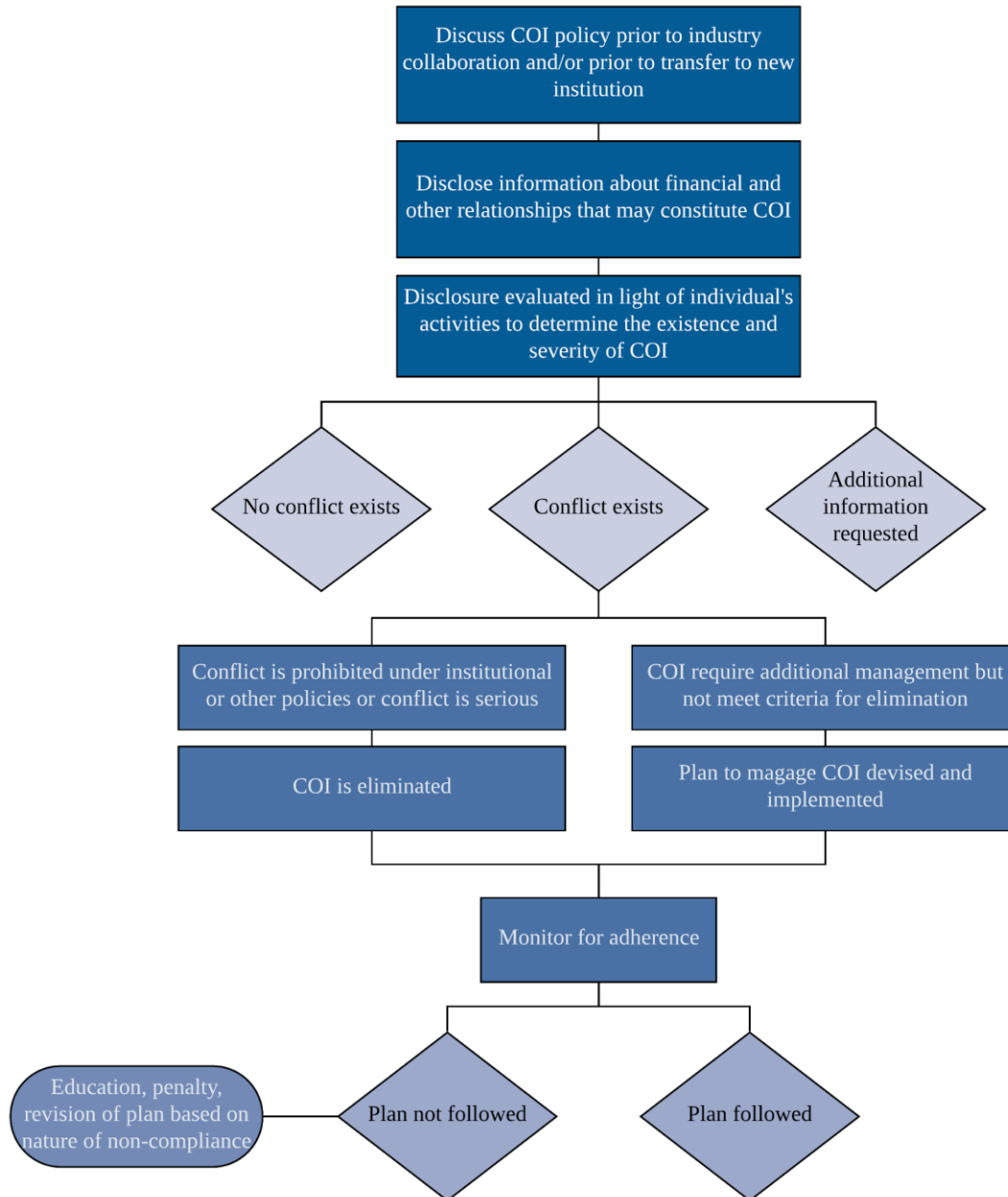
Management of COIs for Clinicians

Clinicians—such as physician-scientists or other healthcare providers—who also pursue academic entrepreneurship should pay additional attention to COI matters when dealing with patients and medical trainees. Quite often, for example, physician-scientists are subject matter experts in the field of their research interest. Therefore, their patient population often consists of those with that specific disease or those who require specific diagnostic or treatment modalities with which the physician may have a COI. This leads to a circumstance of possible influence on clinical decision-making, which the physician must disclose to the patient. Such situations are complex, and research has shown that patients may not fully understand the implications of potential COIs even after disclosure.

Physician-scientists often work in academic institutions and typically also have responsibilities of teaching medical students, residents, nurses, and other healthcare professionals. They are expected to present data and scientific literature in an unbiased manner. They are also expected to teach methods to critically evaluate scientific evidence and exercise independent judgments. In this role, they also serve as role models and thus carry a longer-lasting responsibility to manage and disclose any COIs they may have.

Finally, physician-scientists with subject matter expertise are often members of clinical committees responsible for the development of clinical practice guidelines. Generally, individuals with conflicts of interest are prohibited from guideline-developing panels. However, if exclusion is not possible due to expertise, then other measures are instituted to limit the likelihood of undue influence, such as having a chair of guideline development who has no COI, limiting individuals with conflicts of interest to a small minority of the panel membership, precluding such individuals from voting on topics in which they have a financial interest, involving the public in attempts to identify experts without conflicts of interest, and disclosing any conflicts of interest of those on the panel. Furthermore, most journals require that all clinical practice guidelines accepted for publication describe the developers’ COI policies, the sources and amounts of funding for the guidelines, and the relevant financial interests of guideline panel members, which adds a layer to prevent any real or perceived bias (Korn and Carlat).

Figure 1. Algorithm for Management of Conflicts of Interest



Conclusion

COI analysis and management are a complex but important requirement for the academic entrepreneur. Past experiences have shown that circumstances arising from academic and industry partnerships have caused financial and nonfinancial secondary interests to compromise the primary goals of research integrity and patient safety, either consciously or unconsciously. Individuals can

mitigate these risks by understanding and applying the principles of COI management and focusing on advancing their research goals in a manner that limits real or perceived bias. An understanding of institutional COI policies as well as early and frequent communication with COI committees are key to all academic entrepreneurial endeavors.

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Resources

1. Conflict of Interest in Medical Research, Education, and Practice
Committee on Conflict of Interest in Medical Research, Education, and Practice.
“Conflict of Interest in Medical Research, Education, and Practice.” Institute of Medicine of the National Academies, 2009,
<http://www.nationalacademies.org/hmd/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx>.
2. Public Health Service regulations
”Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought.” Final rule in the Federal Register:
<https://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.
3. Association of American Medical Colleges (AAMC) publications on individual and institutional COIs: <https://www.aamc.org/initiatives/research/coi/>.

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