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Publishing patient information in case reports

-- Joe Munch

As stipulated in the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), authors must obtain—and sufficiently document—permission to publish protected health information (PHI), which is patient health information paired with patient-identifying information. In many instances, such as in reports of retrospective studies, PHI can be sufficiently de-identified to leave only the relevant health information, which can be published without permission and without violating patient privacy.

But in case reports, which often describe the history, symptoms, diagnoses, treatments, and outcomes of a single person, even removing the names, medical record numbers, and other identifiers may be insufficient to safeguard patient identity. Given the level of detail in such articles, people familiar with the patient's case (including the patient) could easily identify the patient.

To de-identify PHI, HIPAA requires the removal of all uniquely identifying patient characteristics. "A rare clinical event, like giving birth to an unusually large number of children at the same time, could become an identifying characteristic of the patient because the clinical event only occurs to a few people, and maybe only once every few years," said Matt Bourgeois, a legal officer in MD Anderson's Institutional Compliance Office. "Rare clinical events are often the subject of case reports, and therefore extra caution should be taken when considering whether the patient is identifiable."

Additional considerations apply when permission is obtained to publish patient information in case reports:

- For case reports that include any PHI, the patient's (or legally authorized representative's) consent to publication of PHI must be documented using the Authorization for the Use and Disclosure of Protected Health information (PHI) - Education and Scientific Publications. This form, also known as a "HIPAA Authorization," can be found in ClinicStation and in FormsAnywhere.

- For case reports that include visual PHI specifically—photographs, radiologic or magnetic resonance images, or videos of the patient that are not de-identified—a HIPAA Authorization is necessary but not sufficient. A Media Authorization and Release must also be used to document the patient's (or legally authorized representative's) consent to publication of such material.

- For case reports that do not include PHI, a signed HIPAA Authorization should be obtained if there is any chance that the patient or the patient's family members or friends could recognize the patient if they read the case report.

In addition, some journals now require the patient's permission to publish a report of the patient's case. For example, *Anesthesia & Analgesia Case Reports* stipulates that submitted case reports, with a few exceptions, "must include a statement that the patient and/or the patient's family reviewed the case report and gave written permission for the authors to publish the report." *JAMA* requires that a submitted case report be accompanied by "[a] signed statement of informed consent to publish . . . patient descriptions, photographs, video, and pedigrees should be obtained from all persons (parents or legal guardians for minors) who can be identified (including by the patients themselves) in such written descriptions, photographs, video, or pedigrees" and that "[s]uch persons should be offered the opportunity to see the manuscript before submission."

Often, the journal will supply a form to document the patient's permission to publish the case. If no form is available, a HIPAA Authorization (with a Media Authorization and Release, if the case report includes visual PHI) can be used instead.

In summary, the patient's permission to publish the case report should be obtained if there's a chance that anyone, including the patient, could identify the patient after reading the report. A HIPAA Authorization should be obtained for all case reports, and both a HIPAA Authorization and a Media Authorization and Release should be obtained for case reports that contain visual PHI.

Sources

Guidelines for the appropriate use and disclosure of PHI are given in Institutional Policy ADM0401, *Patient Privacy: Uses and Disclosures of Protected Health Information Policy.*

Additional details about obtaining authorization for release of PHI are available in Institutional Policy ADM0396, *Patient Privacy: Authorization for the Use and Disclosure of Protected Health Information Policy*.

Details about de-identifying PHI are included in Institutional Policy ADM1180, *Patient Privacy: De-Identification of Protected Health Information (PHI) Policy.*

The most up-to-date Media Authorization and Release form is available through a link in Institutional Policy ADM1050, *Policy Regarding Use of Institutional Images*.

The Department of Scientific Publications provides additional information about publishing patient information in case reports. For specific questions about publishing patient information in case reports, please contact the Institutional Compliance Office at (713) 745-6636.

Changes to NIH grant policies, grant application forms and instructions, and SF424 guidelines

-- *Tamara Locke*

The National Institutes of Health (NIH) is implementing a number of changes to its grant policies, grant application forms and instructions, and *SF424 (R&R) Application Guide for NIH and Other PHS Agencies*, which will affect 2016 submissions.

These changes have been detailed in a series of individual NIH announcements, which are listed in the NIH notice "NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications" (NOT-OD-16-004).

In his "Open Mike" blog, Mike Lauer, NIH Deputy Director for Extramural Research, highlighted some of the most important policy changes:

- There will be new application requirements and review language focused on increased rigor and transparency to enhance the reproducibility of research findings.

- Less information will be needed in the vertebrate animal section of the application, to remove redundancy with information already included in Institutional Animal Care and Use Committee reviews. (Some of this information will be shifted to the research strategy section.)

- The NIH policy on inclusion of children will be updated to lower the age designation for children to include those younger than 18 years. (The current age designation for children includes those younger than 21 years.)

- For training grants, information requirements will change and reduce the applicant burden.

The changes are being rolled out in two phases:

- **Phase 1** affects grants with due dates on or after **January 25, 2016, and before May 25, 2016.** During this phase, a subset of the policy changes are being implemented. Applicants should continue to use existing forms (FORMS-C) with updated instructions.

  A new SF424 application guide was released on November 25, 2015. Details about this update can be found in the NIH notice "Revised SF424 (R&R) Application Guides and Supplemental Instructions Available for Application Due Dates On and Between January 25, 2016 and May 24, 2016" (NOT-OD-16-029).

  During this transition period, when applicants access the SF424 site, they will need to select the SF424 application guide labeled "Use for due dates on and between January 25, 2016 and May 24, 2016" (which is associated with FORMS-C forms and instructions).

- **Phase 2** will affect grants with due dates on or after **May 25, 2016**, when the implementation will be completed with the introduction of new forms and instructions (FORMS-D) and a revised SF424 application guide. The new FORMS-D forms and instructions will be posted on March 25, 2016. All active Funding Opportunity Announcements will be reissued or updated and will include FORMS-D application packages.

In his blog, Mike Lauer says ". . . it is imperative that you submit your application on the right form package to ensure successful submission"; he also states that the NIH will provide various resources this spring to ensure that applicants submit the correct forms.

Microsoft Word 2013: Tips for using Comments, Change Tracking, and other features

-- Stephanie Deming

In Microsoft Word 2013, commenting and change tracking work a bit differently than they did in previous versions of Word. Here we offer some tips for using these features efficiently, for adjusting line and paragraph spacing, and for optimizing the appearance of Word on your screen.

Using Comments and Change Tracking efficiently

Readers at MD Anderson can view excellent brief videos on comments and change tracking in the Education Center. After logging in, find and launch the course "Navigating and Reviewing Documents in Word 2013," click the link for the Table of Contents for the course, and click the link "Reviewing Comments and Markup in Word 2013." Within that section, two modules are especially helpful: "Inserting and Modifying Comments in Word 2013" (8 minutes) and "Tracking Changes and Reviewing Markup in Word 2013" (9 minutes).

Readers without access to the MD Anderson Education Center can find a clear overview of comments and change tracking in the video "Word 2013: Track Changes and Comments," produced by an educational nonprofit. Microsoft also offers text-based and video training on Track Changes.

One particularly helpful tip: to toggle between the All Markup and Simple Markup views in Word, click the red change lines that appear in the left margin.

Changing line and paragraph spacing to increase the amount of text that fits on each page

In Word 2013, the default line spacing is slightly greater than single spacing, and space is automatically inserted after each paragraph. If you are preparing a grant proposal or other document with a strict page limit, you may want to override these default settings to increase the amount of text that fits on each page. For example, you can set the line spacing to single spacing and reduce the space after paragraphs to 0 points.

Changing the capitalization of the ribbon labels

In Word 2013, the labels on the ribbon at the top of the page (e.g., "Insert," "Page Layout," and "Review") appear in all capital letters, which some users find annoying. If you prefer the classic appearance of the ribbon with only the initial letter of each label capitalized, you can apply that style quickly and easily.

Removing pictures next to comments

Word 2013 can display a picture of each commenter alongside his or her comments. If you prefer a more streamlined appearance without such pictures, go to the Review tab, click the down arrow at the bottom right of the Tracking section of the Review tab, uncheck the "Picture by Comments" box in the dialog box that opens, and click "OK" at the bottom of the dialog box.

Citing unpublished material in a research paper

-- Amy Ninetto

You may occasionally find yourself needing to cite your own or someone else's preliminary data, conference presentation, or not-yet-published manuscript in a research paper. Journals' rules on whether and how you should cite unpublished material differ, but there are some general principles to guide you.

First, what constitutes "unpublished material"? The American Medical Association's style manual considers unpublished material to be "articles or abstracts that have been presented at a society meeting but not published and material accepted for publication but not published" (1). Other kinds of unpublished material include preliminary data (either collected by you or shared by another group) and personal communications (conversations, letters, and emails). In most cases, it's okay to refer to unpublished materials in your manuscript, though they should be cited sparingly.

It's important to understand the differences between the types of unpublished material. "In preparation" generally refers to a manuscript that exists in draft form but has not yet been submitted for publication or one that has been submitted to a journal but not yet accepted. "In press" and "forthcoming" refer to papers that have been accepted but not yet published. The ICMJE guidelines, used by most journals, offer some general rules for citing these kinds of materials. "In press" articles should simply be cited like any other journal article; that is, with a number in the text and a corresponding item in the reference list. Instead of the volume and page numbers, however, you'll write "In press." For conference presentations, list the authors, the title of the presentation, the name of the conference, the location, and the date in the reference list.

Other types of unpublished materials—papers in preparation, unpublished or preliminary data, and personal communications—should not be included in the reference list but must be cited parenthetically in the text. For papers in preparation, *Nature,* for example, recommends using the names of the first three authors (plus *et al*. if necessary) and the manuscript's title. Unpublished data and personal communications should be cited in the text thus: "A similar pattern has been observed by A. B. Smith (written communication, January 2016)." If the unpublished data are yours, you can simply use your initials: "(A.B.S., unpublished data, 2016)."

Some journals restrict how unpublished data and personal communications may be used. *Science Translational Medicine*, for example, stipulates that "unpublished data and personal communications cannot be used to support claims in a published paper." That is, you may cite unpublished material if you are discussing the relationship of your study to others (for example, in the Introduction or Discussion), but you may not base your conclusions on or develop your argument using data that hasn't yet become publicly available.

To guarantee that credit and priority are correctly and fairly attributed, most journals, including *JAMA*, *JNCI*, and *BMJ*, require written permission from authors to use their unpublished material. Some journals may require unpublished data to be included in the Supplementary Materials or deposited in an appropriate database so that other researchers can access them. *Science* will defer publication of your accepted paper until all "in press" references have been published.

To determine the best practice for using unpublished material in your manuscripts, read your target journal's author instructions carefully. If you have any questions about specific policies or about your case, don't hesitate to contact the journal's editor.

Reference

(1) *AMA Manual of Style*, 10th ed. New York: Oxford University Press; 2007: 59

Winter and spring schedule for the Research Medical Library webinar program

-- Jill Delsigne-Russell

The Research Medical Library is offering webinars that can help you brush up your skills and get organized for a new year of research and discovery. You can participate in the live webinars or access past webinars in the library's archives.

Recent Webinars:

Creating a Data Management Plan
Researchers requesting federal funds are required to develop data management plans and describe how they will provide for long-term preservation of and access to data resulting from research. Data management plans describe the data to be collected and the metadata to make that data accessible and include provisions for protecting privacy and intellectual property. This webinar, recorded on November 12, 2015, provides an overview of common elements of a data management plan with specific examples; it also includes tools to help create a data management plan.

EndNote Online
Recorded on December 8, 2015, this webinar covers EndNote Online, a web-based version of EndNote that can be accessed from anywhere without a VPN. EndNote Online can be used to collect and organize references, share groups of citations, and format citations. All MD Anderson employees and students can create a free EndNote Online account while on campus.

PubMed in 30
This webinar, recorded January 27, 2016, is mostly for PubMed rookies, but seasoned veterans may pick up a thing or two as well. Basic searching and navigation skills are demonstrated, including thinking about your search strategy, narrowing down search results, finding full-text sources, and requesting items when the Research Medical Library doesn't have access.

Upcoming Webinars:

Dr. Google, Mr. PubMed
February 17, 2016, 11:00 am-11:30 am
This webinar will explore the good, the bad, and the ugly of searching Google, Google Scholar, and PubMed. Join us to learn how to search PubMed and Google effectively.

PubMed Central Reference Numbers (PMCIDs) and the NIH Public Access Policy
March 15, 2016, 11:00 am-11:30 am
What is the NIH Public Access Policy? Do I need a PMCID? Does my article (or another author's article that I'm interested in citing) already have a PMCID? How do I get a PMCID for my article? This webinar will help you answer these questions.

Design Tips for Posters
April 28, 2016, 11:00 am-11:30 am
Are you submitting a research poster for a professional conference? This webinar will cover tips and tools to help you plan and design your poster.

Digital Tools for Educators
May 24, 2016, 1:00 pm-2:00 pm
This webinar will demonstrate some practical technologies that can be used to enhance your classes or training sessions. The focus will be on tools for modifying digital images and creating screen captures and videos, as well as copyright and fair use of online materials. The webinar will also review tools for asynchronous presentations and training sessions, polling and quizzing tools, and a plagiarism detection tool.

Quality Health Information Resources for Your Patients
May 25, 2016, 10:00 am-11:00 am
Millions of patients search the web daily for health information. Sometimes the information they find is just what they needed. At other times, however, their searches result in the retrieval of inaccurate, even dangerous, information. Join us to learn about quality health information resources available for your patients.

To register for a webinar, please visit the library's Class Calendar. Webinars are color-coded red. When you click on the link for the webinar, you will be directed to the registration screen.

Unusual terms used in scientific writing and publishing: Uniform requirements/ ICMJE recommendations

-- Bryan Tutt

If you've heard the terms "uniform requirements" and "International Committee of Medical Journal Editors (ICMJE) recommendations" but aren't sure exactly what they are, here is your answer: the two terms refer to the same document. Originally published in 1978 as *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, the document has since been revised several times and retitled *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*. The current 17-page document of ICMJE recommendations is available in html and PDF formats at the ICMJE website.

The ICMJE recommendations provide both editorial and ethical guidance for all stages of writing and publication. The section on preparing a manuscript for publication explains what information should be included in each section of a journal manuscript—not only the introduction, methods, results, and discussion sections but also the abstract, references, tables, and figures. In addition, the ICMJE recommendations address copyright issues and other concerns such as retractions, corrections, and overlapping publication; the document also defines the roles and responsibilities of authors, peer reviewers, and editors.

Authors of journal manuscripts can make the writing and publishing process go more smoothly by checking the ICMJE recommendations before they begin writing and keeping the document on hand to answer questions as they arise. You can learn more about the ICMJE recommendations in the Spring 2005, Autumn 2013, and Spring 2015 issues of *The Write Stuff.*

Upcoming events for authors

Please see the Scientific Publications website for more information on our educational courses.

Write Winning Grants Seminars
The Department of Scientific Publications is bringing back to MD Anderson the widely acclaimed seminar series "Write Winning Grant Proposals" and "Write Winning NIH Career Development Award Proposals," presented by John D. Robertson, PhD, of Grant Writers' Seminars and Workshops, LLC. The two seminars address both practical and conceptual aspects of the proposal-writing process.

Seminar 1, Write Winning Grant Proposals, April 4, 2016

This seminar, based on NIH grant application guidelines, will help you:

- write for reviewers and “sell” your proposal;
- develop ideas and organize your presentations using linear progression of logic to guide reviewers through your application; and
- write for two different reviewer audiences—those who have read the entire application before the review meeting and those who have not—and develop advocacy for funding in both groups.

Seminar 2, Write Winning NIH Career Development Award Proposals, April 5, 2016

This seminar will focus on individual mentored training grants and career development awards and is recommended for trainees, junior faculty members, and their mentors and/or advisors.

Attendees of both seminars will receive extensive handouts, including the slides and examples used during the seminars, as well as a copy of *The Grant Application Writer’s Workbook.*

For more information about Grant Writers’ Seminars and Workshops, LLC, visit www.grantcentral.com.

Priority registration for MD Anderson faculty and staff is currently open and will last until **Friday, February 6, 2016**. The seminars will then be offered to people from other TMC institutions. Final cutoff for registration is **Friday, February 19, 2016**.

You can register online at www.mdanderson.org/conferences. Details: John McCool (*jhmccool@mdanderson.org*), 713-792-3174.

Short Courses in Scientific English for Non-Native Speakers of English. Courses last 7 weeks and meet twice a week for 1 or 1.5 hours each day. Classes are held early in the morning, during the lunch hour, or late in the afternoon. Classes are free of charge. Participants must speak English at the intermediate or higher level and be familiar with research and general biomedical terminology. Dates are subject to change. Details: Mark Picus (*mapicus@mdanderson.org*), 713-792-7251, or John McCool (*jhmccool@mdanderson.org*), 713-792-3174.

> **Session 1 – January 26 through February 23, 2016**
> **Pronunciation 1, Conversation 1, Conversation 2, Making Presentations, Writing 1**
>
> **Session 2 – March 7 through April 26, 2016**
> **Pronunciation 1, Pronunciation 2, Conversation 1, Conversation 2, Writing 2**

Friday Conversation Group. The Friday Conversation Group provides an informal atmosphere for non-native speakers of English to practice their conversational abilities, learn more about American culture, and meet new friends. The class meets every Friday in the Mitchell Building (BSRB), room S3.8003, from 12:00 to 1:00 pm. No registration is required. Details: Mark Picus (*mapicus@mdanderson.org*), 713-792-7251, or John McCool (*jhmccool@mdanderson.org*), 713-792-3174.

Writing and Publishing Scientific Articles (WAPSA). WAPSA is a structured, practical, and in-depth writing-education program for postdoctoral fellows and clinical trainees at MD Anderson taught by the Department of Scientific Publications. This 16-contact-hour course provides an excellent opportunity for advancing participants' skills in writing and publishing research articles while developing their in-progress manuscripts under the guidance of scientific editors.

Locations and times to be announced. Registration required through the Department of Scientific Publications. Details: John McCool (*jhmccool@mdanderson.org*), *713-792-3174.*

May 3 & 10, 2016

Writing Scientific Articles (WSA): A Workshop for Faculty. WSA is a structured, practical, and in-depth writing-education program for clinical and basic science research faculty at MD Anderson taught by the Department of Scientific Publications. This 1-day, 8-contact-hour course provides an excellent opportunity to advance your skills in writing research articles with focus and clarity.

Locations and times to be announced. Registration required through the Department of Scientific Publications. Details: John McCool (jhmccool@mdanderson.org), 713-792-3174.

February 25, 2016

Writing Persuasive R01 Proposals. This newly developed grant-writing workshop for clinical and basic science research faculty at MD Anderson focuses on the content, organization, and structure of an R01 grant application. Taught by senior editors in the Department of Scientific Publications, this 1-day workshop includes lecture, discussion, and guided grant outlining and development.

Locations and times to be announced. Registration required through the Department of Scientific Publications. Details: Teasha Barker (tsbarker@mdanderson.org), 713-792-6019.

February 23, 2016

Grant Writing Advice. The Department of Scientific Publications now offers grant writing suggestions (Writing R01 Grant Proposals) in the Writing Advice section of our website. This information, stemming from the Grant Writers' Seminars and Workshops (developed by Drs. Stephen Russell and David Morrison and presented annually at MD Anderson) and from the NIH's SF424 (R&R) Application Guide, focuses on R01 grants but can be applied to other types of NIH grants as well.

Writing the Specific Aims Section of a Grant Application. In this video, Scientific Editor Sunita Patterson presents a summary of the National Institutes of Health's grant-review process and how it affects the grant proposal, an overview of the structure of an R01 grant proposal, and a model for writing the Specific Aims section. The video is available on the Scientific Publications website.

Writing Abstracts Online Tutorial. Writing Abstracts, an interactive, Web-based tutorial, covers the most important aspects of writing good abstracts. The lesson includes many examples and an optional self-assessment.

Improve Your Chances for IRG Funding. This PDF presentation by Walter Pagel, the former Director of the Department of Scientific Publications, guides researchers through the process of applying for institutional research grants.

Anatomy of a Research Article Video Presentation. In this video, Senior Scientific Editor Stephanie Deming presents advice on writing the parts of a research article: Introduction, Methods, Results, Discussion, title, and abstract. The slides shown in the presentation and the presentation handout can be downloaded as well.

Classes Presented by the Research Medical Library. More classes will be posted on the Research Medical Library website once they have been finalized. Classes are located in the Research Medical Library classroom in the Pickens Academic Tower (FCT21.6008). Details: Laurissa Gann (*lgann@mdanderson.org*), 713-794-1111.

February 2, 9:00 am, EndNote Basics (Pickens, Floor 21)
February 4, 12:00 pm, Library Essentials for Administrative Assistants (Pickens, Floor 21)
February 9, 9:00 am, EndNote Advanced (Pickens, Floor 21)
February 17, 11:00 am, Webinar: Dr. Google, Mr. PubMed
February 24, 11:00 am, PubMed Basics (Pickens, Floor 21)
February 25, 9:30 am, Systematic Reviews: Planning the Literature Search (Pickens, Floor 21)
March 2, 11:00 am, EndNote Basics (Pickens, Floor 21)
March 9, 11:00 am, EndNote Advanced (Pickens, Floor 21)
March 15, 11:00 am, Webinar: PMCIDs and the NIH Public Access Policy
March 24, 10:00 am, Library Essentials for Administrative Assistants (Pickens, Floor 21)
March 29, 2:00 pm, PubMed Basics (Pickens, Floor 21)
April 1, 10:00 am, EndNote Basics (Pickens, Floor 21)
April 6, 1:00 pm, Literature Reviews: Searching for Evidence (Pickens, Floor 21)
April 7, 10:00 am, EndNote Advanced (Pickens, Floor 21)
April 26, 9:00 am, PubMed Basics (Pickens, Floor 21)
April 28, 11:00 am, Webinar: Design Tips for Posters
May 24, 1:00 pm, Webinar: Digital Tools for Educators
May 25, 10:00 am, Webinar: Quality Health Information Resources for Your Patients

All Research Medical Library classes require preregistration through the “Classes & Webinars” section of the Library’s website. MD Anderson employees should register through the Education Center. For class descriptions and printable handouts or calendars, go to the Research Medical Library’s Library Classes page.