

**MEDCOMMS NETWORKING  
BRUNCH CLUB  
14 JUNE 2017**

**CAUDEX**

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**THE CORPORATE AUTHOR**

**JACKIE MARCHINGTON  
DIRECTOR OF GLOBAL OPERATIONS,  
CAUDEX**

# DISCLOSURES

- The views and opinions expressed today:
  - are not necessarily those of my employer
  - are based on personal experience
  - do not constitute legal advice

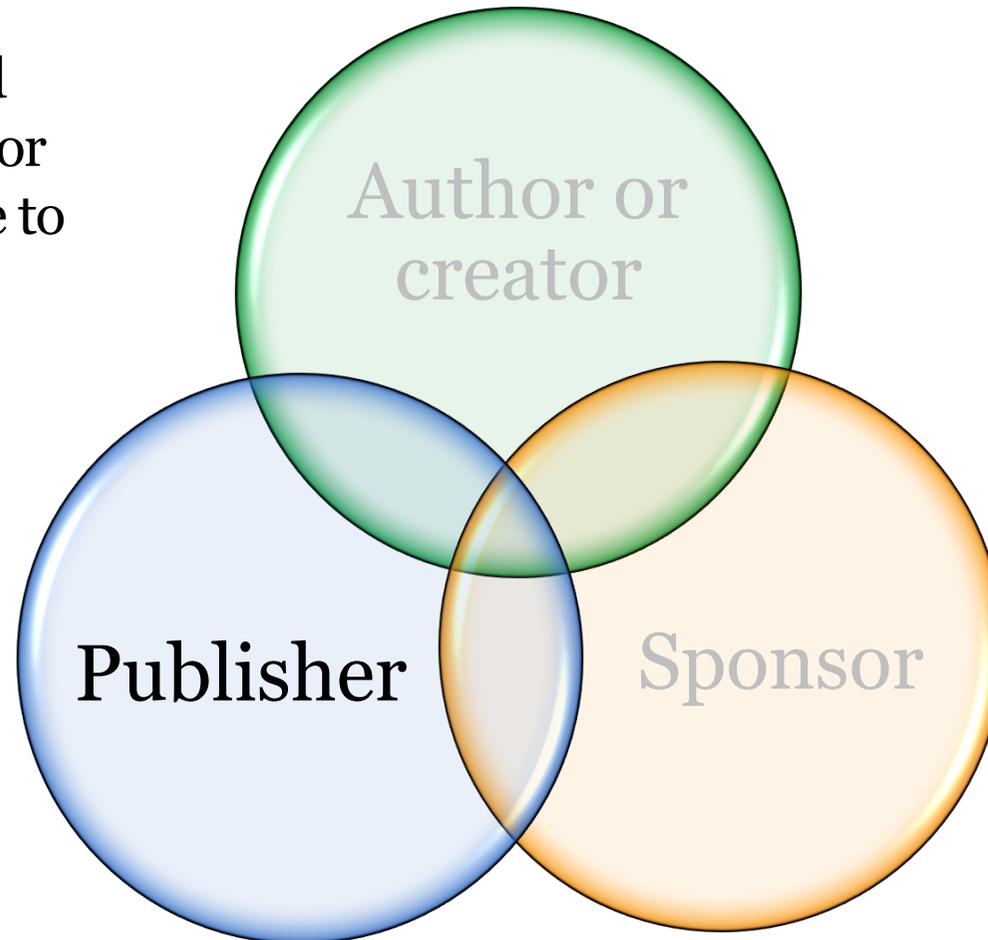
# COPYRIGHT IN PUBLICATIONS

- Most pharmaceutical companies have policies along the lines of Good Publication Practice (GPP)<sup>1</sup> for handling publications
- Policies are designed around publication ethics, data disclosure and transparency
- Copyright doesn't really fall into either of these categories and is often missed in terms of compliance guidance
- Most people think of copyright in terms of permission (e.g. for promotional usage) rather than possession (content generation)

<sup>1</sup> Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Intern Med.* 2015;163:461–464.

# COPYRIGHT STAKEHOLDERS

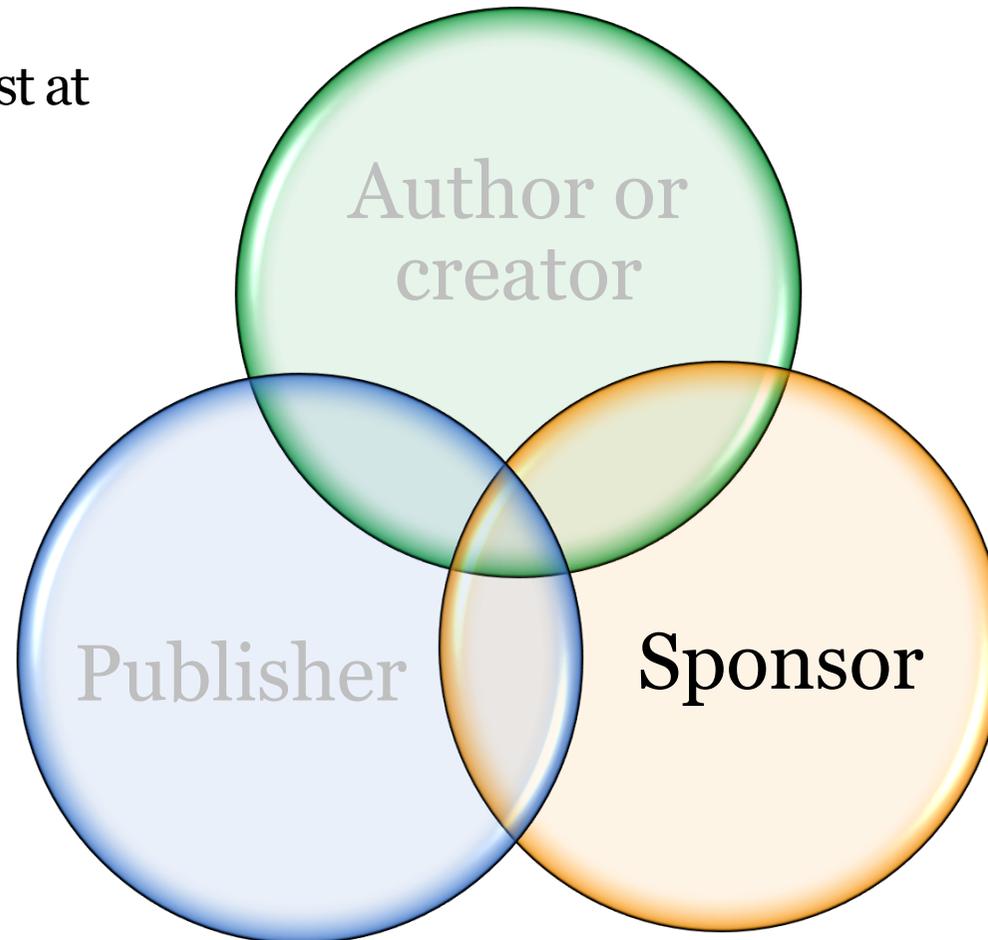
Good old fashioned  
copyright transfer, or  
an exclusive licence to  
publish



Copyright transfer is the price authors pay for traditional publishing.  
Traditional publishers publish at little or no cost to the author, but require  
the rights to exploit your work commercially

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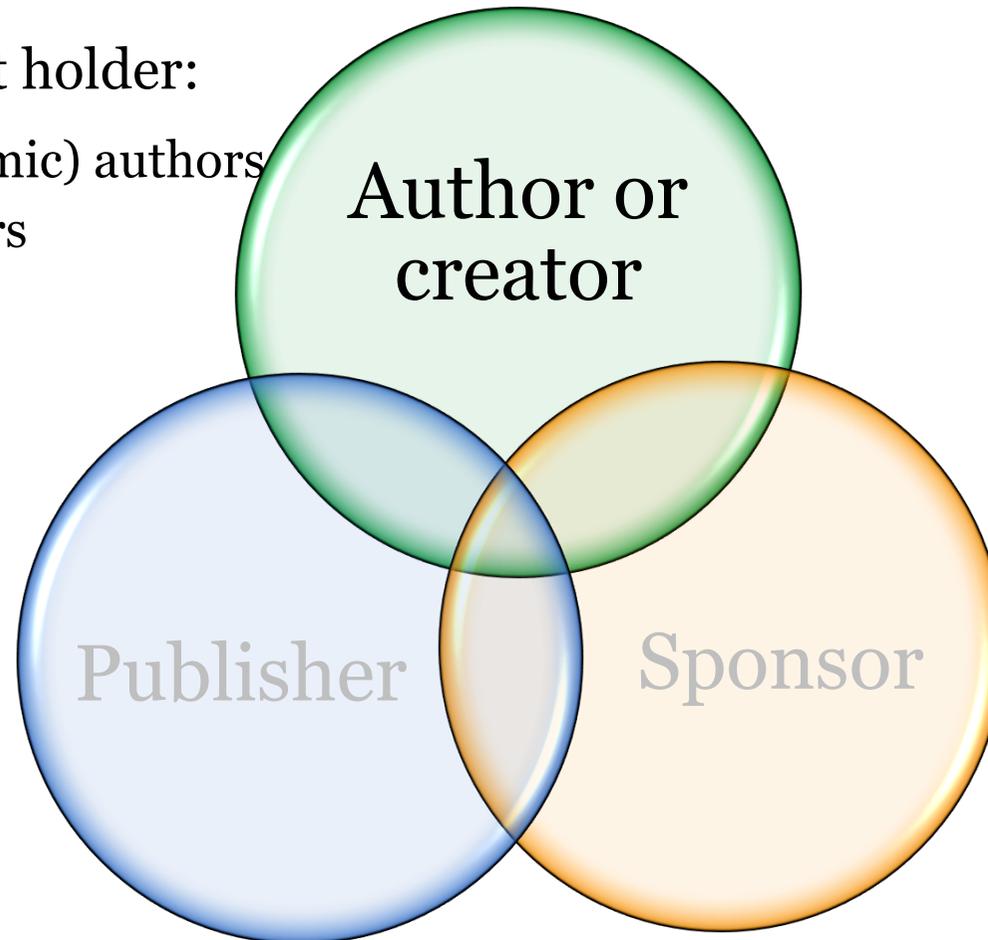
No copyright interest at all, if all external (academic) authors



# COPYRIGHT STAKEHOLDERS

Original copyright holder:

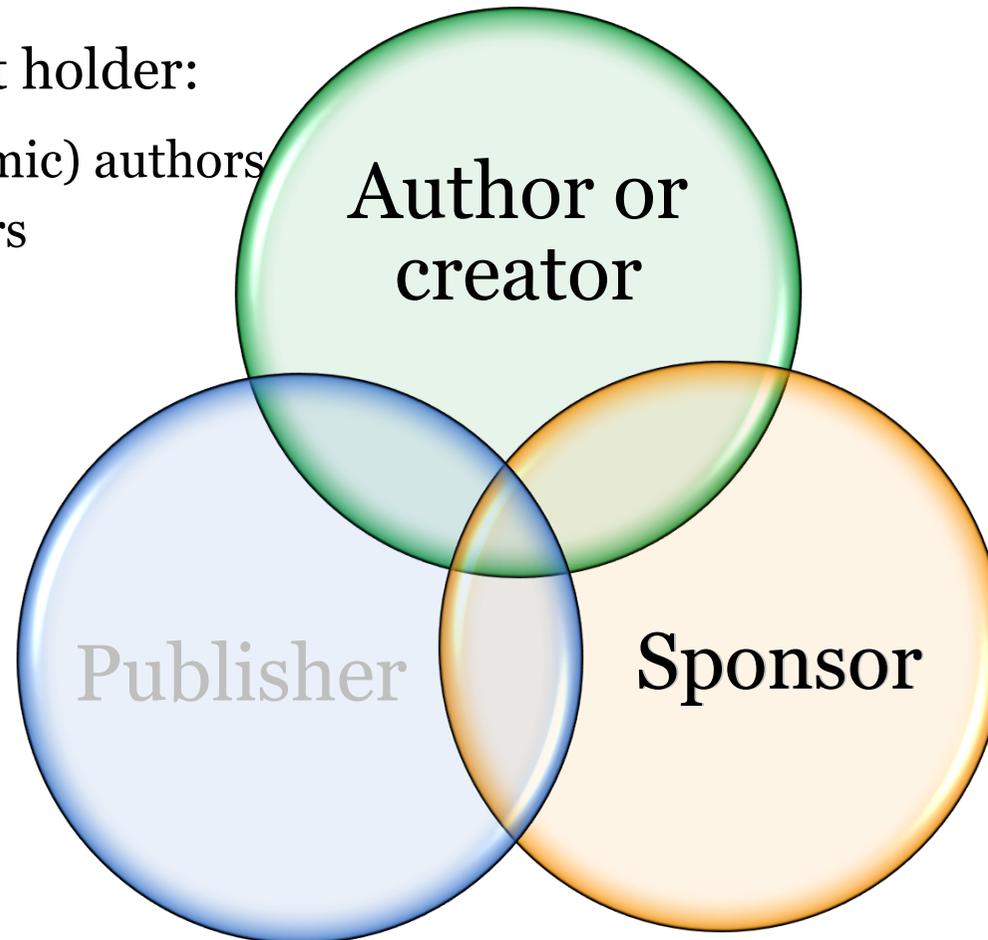
- External (academic) authors
- Company authors
- Vendor authors



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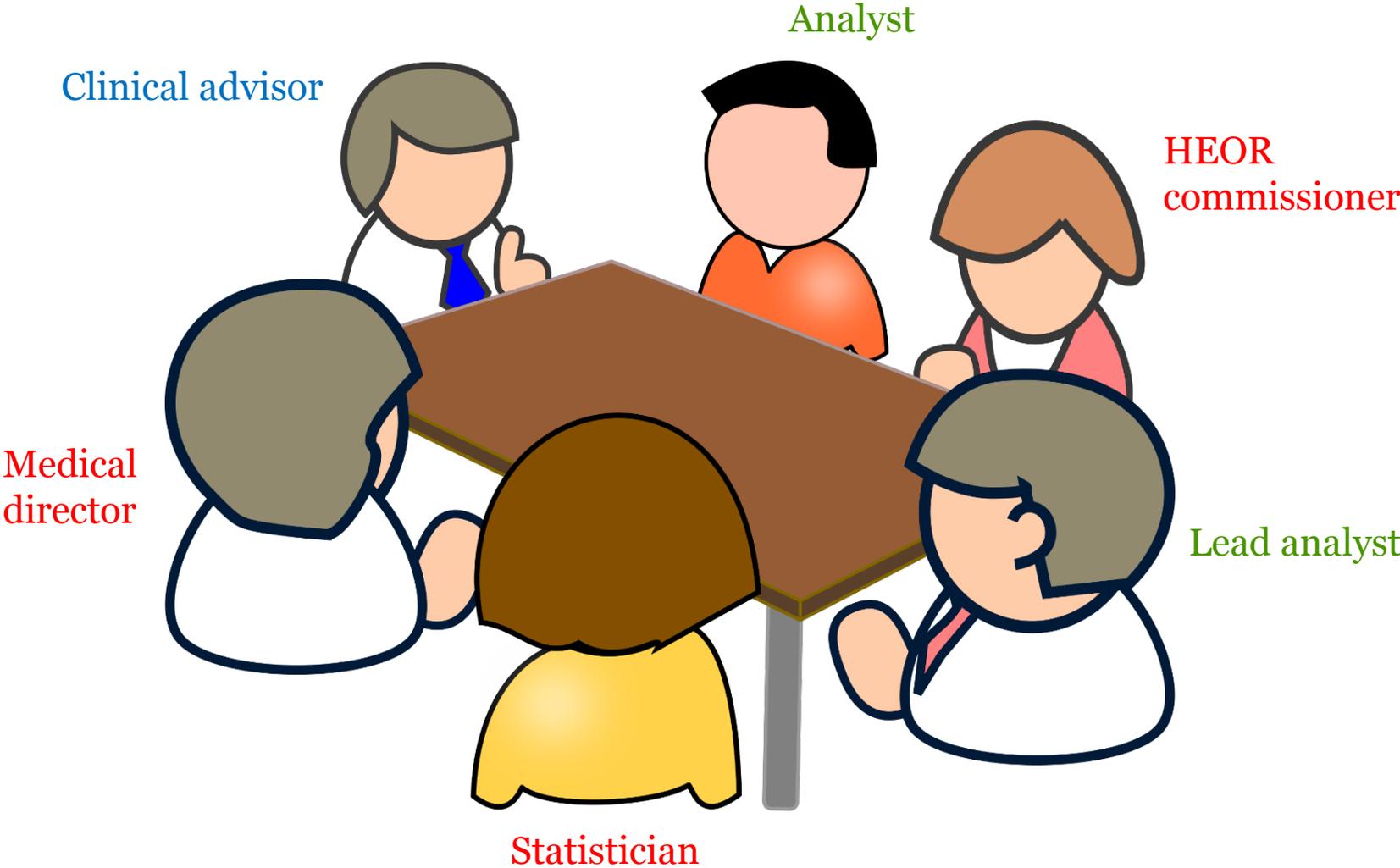


If the work was created as part of your employment, then it is most likely a “work made for hire”

# CO-AUTHORS: CLINICAL



# CO-AUTHORS: HEOR/RWE



# WHAT IS WORK MADE FOR HIRE?

- US legal term. *Work for hire* is a statutorily defined term (17 U.S.C. § 101)
  - a work subject to copyright that is created by an employee as part of his/her job, or some limited types of works for which all parties agree in writing to the WFH designation
- UK: Works created for an employer
  - Where a literary, dramatic, musical or artistic work, or a film, is made by an employee in the course of his employment, his employer is the first owner of any copyright in the work (subject to any agreement to the contrary)
  - ‘contract of service’ (an employee) vs ‘contract for services’ (a freelancer or independent contractor)

# WORK MADE FOR HIRE?

- You have been invited by a journal editor to write a review for his/her journal

# WORK MADE FOR HIRE?

- You have been invited by a journal editor to write a review for his/her journal
- Not work made for hire – this is a solicited review from the journal and you are not being paid by them
- However, if you write it as part of your duties as an employee, then your employer *may* own your work
- If you're writing it in your own time, or independently of your employer, then it's not work made for hire

# WORK MADE FOR HIRE?

- You have been invited by a journal editor to write a review for his/her journal ✗
- You are an investigator in a clinical trial (for which your department received funding from the sponsor) and are participating in the writing of the paper

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- You are an investigator in a clinical trial (for which your department received funding from the sponsor) and are participating in the writing of the paper
- Not work made for hire – your department received funding for the trial, not the publication, and you are not being paid to participate in the writing
- It's not part of your duties as an employee, it was a grant-funded study, so it's not work made for hire
- If you are doing this in work time, your employer *may* claim a stake

# WORK MADE FOR HIRE?

- You have been invited by a journal editor to write a review for his/her journal X
- You are an investigator in a clinical trial (for which your department received funding from the sponsor) and are participating in the writing of the paper X
- You are an agency medical writer who qualifies for authorship on a review paper

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- You are an agency medical writer who qualifies for authorship on a review paper
- Definitely work made for hire. You are employed as a writer, so your contribution belongs to your agency, and most likely, via your agency's contract with their client, goes to the sponsor

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- You are a research analyst for an HEOR agency and are writing up the analysis you performed with your client, for publication

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- You were an investigator in a clinical trial (for which your department received funding from the sponsor). You are now between contracts and the trial sponsor is reimbursing you for time spent working on the paper

# WORK MADE FOR HIRE?

- You were an investigator in a clinical trial (for which your department received funding from the sponsor). You are now between contracts and the trial sponsor is reimbursing you for time spent working on the paper
- Not employed, so no consideration for work made for hire
- Are being paid by sponsor, so depends on what your agreement with the trial sponsor says

# WHY DOES IT MATTER?

- After acceptance of a manuscript for publication, authors enter in to a contract with a publisher to have the work published
- This may entail:
  - Assertion that the research is original and not published elsewhere
  - Assertion that the work is accurate and indemnification of the publisher against damages arising from breach of any of the publishing conditions
  - Transfer of copyright
  - Execution of publishing agreements
- You need to have the legal authority to do this

# COPYRIGHT TRANSFER FORMS

## COPYRIGHT TRANSFER AGREEMENT

JOURNAL: [REDACTED]

WORKING TITLE OF CONTRIBUTION: \_\_\_\_\_

CORRESPONDING AUTHOR \*: \_\_\_\_\_ AUTHOR: \_\_\_\_\_

AUTHOR: \_\_\_\_\_ AUTHOR: \_\_\_\_\_

\* The "Corresponding Author" is authorized to communicate with [REDACTED] and the Editor of the Journal on behalf of all the Authors.

### CHECK ONE:

- Author owned work**
- Work made for hire for employer** – the Contribution was prepared by the Author within the scope of his/her employment and copyright in the Contribution is owned by the Author's employer. Both the Author and an authorized representative of the Author's employer must sign this Agreement. Please indicate "Employer":  
\_\_\_\_\_
- U. S. Government work** – the Author is an employee of the United States Government and prepared the Contribution as part of his/her official duties. If the Contribution was not prepared as part of the Author's official duties, it is not a U.S. Government work. If the Contribution was jointly authored, all the co-authors must have been United States Government employees at the time they prepared the Contribution in order for it to be a U.S. Government work; if any co-author was not a United States Government employee, then the Contribution is not a U.S. Government work. If the Contribution was prepared under a U.S. Government contract or grant, it is not a U.S. Government work (in such case, copyright is usually owned by the contractor or grantee).

No, I don't have permission to reproduce this . . . I'm going for "fair criticism and review"

# COPYRIGHT TRANSFER FORMS

## **Joint**

- Corresponding author often signs on behalf of co-authors
  - What if co-authors are company employees?
  - What if corresponding author is a company employee (e.g. HEOR, not only an employee but often a vendor)?
    - Author
    - Author's employer (vendor)
    - Vendor's employer (company)

## **Individual**

- Academic authors sign own
- Corporate authors need an authorized signatory
- Vendor authors need an authorized signatory

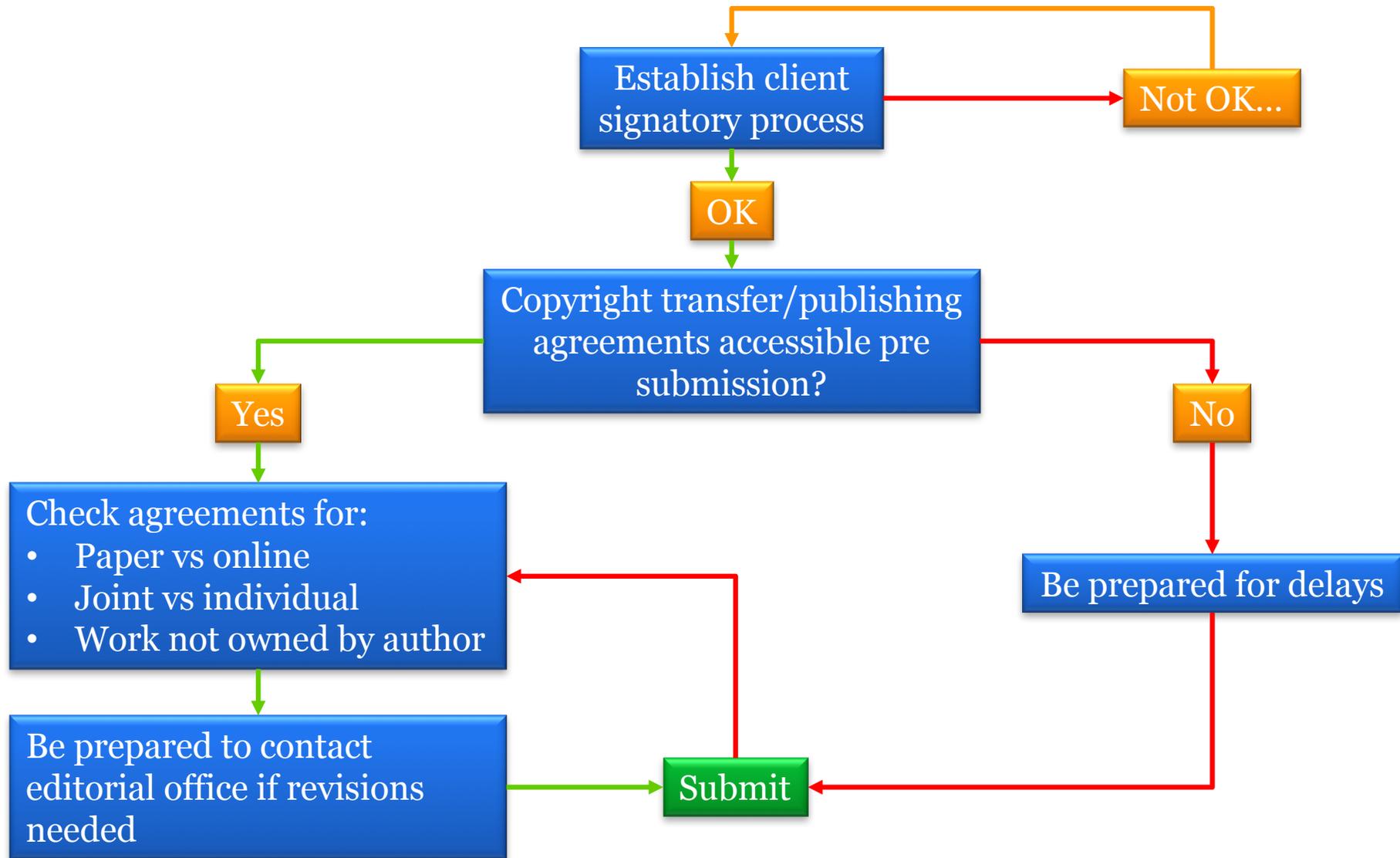
## PRACTICALLY...

- Ignorance of “work made for hire” requirements among staff and vendors
- Even if there is an authorized signatory process in place, publication compliance may not be aware of it
- Everybody hates copyright
- Easier to ignore it, or not ask the question . . .
- Most Agency–Client Master Services Agreements usually include some wording around copyright compliance and helping our clients to remain compliant

# THINGS TO THINK ABOUT

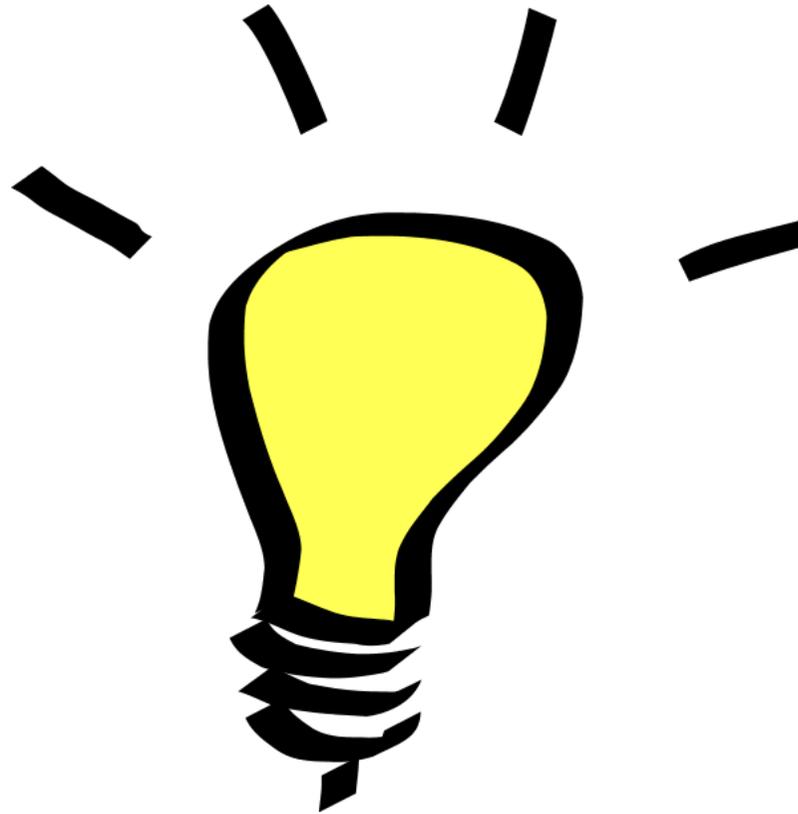
- Who is an authorized signatory?
  - Whoever Legal says, really . . .
    - Global Publications Lead
    - IP Lead in Legal
- GPP3 clarifies that authors can be paid for working on publications
  - Will only be a “work made for hire” if specified in the author contract/agreement
- Vendor agency staff

# WORKFLOW



AHA!

- I know, let's make it open access, then we don't have to do a copyright transfer!



# NOT WHAT YOU MIGHT THINK . . .

- Variation in how “open” open access is
- Many “OA” publishers allow public access but retain copyright (so copyright transfer is still required)
- Many mainstream publishers allow authors to retain copyright, but require an “exclusive licence to publish”
- Under a CC BY-NC licence, transfer of commercial rights to the publisher is often required
  
- All these agreements need to be executed by an authorized signatory in the case of company authors

# SUMMARY

- Build copyright compliance in to your publications SOPs and workflow
- Designate authorized signatories who understand publications
- Review vendor author practices, ensure appropriate signatory process is in place
- Read the small print
  
- Life as a corporate author can be tricky, but it's easier if you plan ahead!

# THANK YOU

[JACKIE.MARCHINGTON@CAUDEX.COM](mailto:JACKIE.MARCHINGTON@CAUDEX.COM)

[WWW.CAUDEX.COM](http://WWW.CAUDEX.COM)



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