

SOM Office of Grants & Contracts:
Submitting Your NIH Grant Proposals
What NIH calls errors or problems

April 21, 2021

Agenda: Successful Submissions to NIH

- **Goal: Improve quality of submissions and save time in award negotiations**
 - This is intended to be a training and update on Other Support and Biosketch
 - This may generate questions for all. We will try to get to them all and may have to provide follow up with answers
- ***Let's pull the curtain back: NIH***
 - **Proposals**
 - **JIT**
 - **RPPR**
- **NIH's Policy Change**
 - **Other Support**
 - **Biosketches**

Issues with Proposals: Red Zoners

- Links and/or URL's
- Budget justification (modular budgets)
- Non Modular detailed budget
 - All are encouraged to ask for more money
 - Ask for all the money YOU need to do the work
 - Salary escalation is not allowed
- Headers/footers in application
- Co-Investigator vs collaborator vs consultant
- Rejections from NIH:
 - IC must be included in the RFA
 - Incorrect RFA reference
 - Budget over \$500,000 without prior permission

Budget Justification

Key Personnel

NAME here, credentials, PI (1.2 Cal. Months annually)

Dr. XXXXX is a Professor at Case Western Reserve University School of Medicine. Dr. XXX is an accomplished b....., and is a leader in the emerging field of He currently serves as a XXXXX committee member and a XXXXX subgroup leader for the international and regular member of the XXXXXX Study Section at NIH. Dr. XXXX will be the PI for the project, and will coordinate all lab meetings and formal interactions with the collaborating groups, XXXXX. He will also supervise and organize the project through mentoring junior members of the research team, writing and/or editing all manuscripts related to the project, working directly in the laboratory primarily on XXXXXXX and to assist junior members of the team, leading data analysis efforts, and overseeing all animal model analyses.

NAME PhD, Co-Investigator (1.2 Cal. Months Year 1-2 and 2.4 Cal Months Year 3-5) is a new tenure-track Assistant Professor of XXXXXX at Case Western Reserve University School of Medicine. Dr. XXXX is an expert on XXXXX biology and XXXX-, including recent landmark findings published in XXXX. He will contribute experience in XXXX biology and be directly involved with helping and advising on XXXXX for this proposal.

NAME PhD, Consultant/Other Significant Contributor (0 Cal. Months) is a Professor and Chair of XXXX. Dr. XXX is a world-renowned expert in the XXXX. He is also responsible for most of what is known for XXXX that are important for this project, including the XXXX. His role will be advisory in nature, and he has agreed to share any needed resources to see this project be successful.

NAME PhD, Co-Investigator (1.2 Cal. Months) is a Senior Staff Scientist in the XXXX laboratory at XXXXX He has been in the XXXXX laboratory for XX years and served as the Director for XXXXX. As such, he is an expert at XXXXX and will be responsible for producing and validating the proposed XXXXXX that will be employed in this research program.

Non-Key Personnel

Senior Scientific Staff (6 Cal. Months) is scientific staff at Case Western Reserve University Medical School who works under Dr. XXX in the Department of XXXX. Ms. XXXX received her master's degree from XXXXX, working in molecular biology, and serves key roles in the laboratory. These roles will primarily be assisting with XXXXX. She is also responsible for general laboratory supply and equipment maintenance.

NAME Technical Staff (6 Cal. Months) is technical staff at Case Western Reserve University Medical School who works under Dr. XXX in the Department of XX. She is the XXXX laboratory animal technician and is in charge of maintaining the XXXXX required for the completion of the proposed studies. She has been in the XXX laboratory for nearly XXX years, and has extensive XXX expertise, having worked for She will be primarily responsible for organizing XXXXXX, coordinating XXXX, and maintaining XXXXX.

Non-Salary Budget

Travel: \$3,000 annually
\$3,000 are requested to offset costs associated with data dissemination at a national or international meeting, such as the XXXXXX annual meetings.

Supplies: \$45,000 annually
\$20,000 XXXX supplies (\$20,000)
\$25,000 Antibodies and related reagents for XXXXX \$25,000

Equipment: \$6,000 (year 1 only); \$0 for all subsequent years
We request \$6,000 to purchase an additional XXXXXXXX

Minor Equipment: \$2,000 (year 1 only); \$0 for all subsequent years
We request funds to purchase an additional -20°C freezer, as we are at capacity with our current freezer.

Animals: \$50,000
There are several animal strains involved with the completion of this proposed project. Explain costs here. Thus \$50,000 is requested.

Publications: \$5,000
This roughly corresponds to three manuscripts a year.

Internal Services: \$12,000
We require access to the Core Facility to perform XXXX and analyses. These funds are requested to pay the hourly user fees.

External/Consulting Services: \$10,000
\$5,000 XXXX Technologies
\$5,000 XXX Sciences; standard XXX seq services

Postdoctoral Insurance: \$6,000

XXXX Subcontract Total Budget (yr 1) \$48,375
\$25,000 Year 1 Direct Costs
\$23,375 Year 1 Indirect Costs

Proposal Suggestions

- Review AIMS with PO
- Application Overlap
- Cover Letters
- No appendices unless RFA allows
- Seriously consider submitting an R01 above \$500K Direct
 - Request permission from NIH 6 weeks prior to submission date
- **Editing/science review assistance**
 - **Reach out to Erin Fogarty (exf132) (docs needed 2-3 wks in advance)**

Submission Day

- **Must** be fully routed to OG&C
 - SPARTA FP (funding proposal) and in Assist or workspace if applicable
 - Sparta: Can be an email posted into SPARTA FP or the PI can indicate it when they route the FP to the Chair
- SOM CWRU policy requires availability of:
 - Department Administrator
 - PI
 - **By phone!**
- New proposal submission policy

JIT

- Verify effort in ongoing support
 - Not the completed projects
- Completed Support
 - No more than 3 years
- List grant in question in pending support !!!!
- Foreign component/collaboration
 - If any, must be disclosed
 - For example: If a new one evolved since the original application
 - Confirmed in the Sparta FP **by the PI**
 - Disclose as needed in Other Support
 - Sparta: Can be an email posted into SPARTA FP or the PI can log comment

JIT

- Human Subjects/Animal use
 - Human Subjects: CREC certificates are required
- Read JIT closely
- Sub F&A agreements are often requested
- Key Personnel changed from proposal?
 - Include needed documents

RPPR Errors

- **Reporting effort**
- **Manuscripts**
- **Human subjects and/or animal use**
- **Questions G.9 and G.10 must be confirmed in SPARTA FP**
 - PI must confirm
- **Reduction of effort for Key Personnel ?**
- **Anything different to report?**
- **(Program Grants): Submit NIH's defined budget amount for future period**



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Case Studies

- GMS (mis) interpretation of guidelines
- RPPR
 - Foreign component disclosed for the first time
- iRPPR
 - Read the NOGA
 - An iRPPR may be required
- Read your NOGA again
- Red Zone submission (s)
 - Budget issues: causes delay



IMPERATIVE

NIH requires communications
originate from AOR (signing official)
PO and PI yes re: science

Reminder: Award

Please be responsive to your department administrator regarding budget and compliance inquiries

Lots of time is lost here

Other Support/Biosketch Changes per NIH

Effective on and after May 25, 2021

Format Page	Changes
Biographical Sketch Format Page	<p>Section B ‘Positions and Honors’ Renamed ‘Positions, Scientific Appointments, and Honors’.</p>
	<p>For the non-Fellowship Biosketch: Section D has been removed</p> <p>For the Fellowship Biosketch: Section D has been updated to remove ‘Research Support.’ As applicable, all applicants may include details on ongoing and completed research projects from the past three years that they want to draw attention to within the personal statement, Section A.</p>
Other Support Format Page	<p>Re-organized to separate funded projects from in-kind contributions</p>
	<p><u>Signature block added</u>, for Program Director/Principal Investigator or Other Senior/Key Personnel to certify the accuracy of the information submitted</p> <p><u>Each PD/PI or senior/key personnel must electronically sign their respective Other Support form as a PDF prior to submission</u></p>

OTHER SUPPORT: Supporting Documentation

- For Other Support submissions that include foreign activities and resources, **recipients are required to submit copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation.**
 - (at least in the last 5 years)
- If they are not in English, **recipients must provide translated copies.** This supporting documentation must be provided as part of the Other Support PDF following the Other Support Format page.
- ORTM is working on a decision tree checklist

Effective Date

- **Due dates on or after May 25, 2021**
 - **Applications and JIIs**
- ***After January 25, 2022***
 - ***NIH will withdraw your application***
- ***SOM OG&C requires the new format effective Midnight 5/24***



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Reminders Other Support:

- Other Support includes all resources made available to a researcher
- This includes but is not limited to:
 - **Resources and/or financial support from all foreign and domestic entities**
 - **Consulting agreements**
 - When the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities. Non-research consulting activities are not Other Support.
 - **In-kind contributions**
 - Office/laboratory space
 - Equipment
 - Supplies
 - Employees or students supported by an outside source.
 - Provide **reasonable estimates of value, if not readily available**
 - **Only resources UNIQUELY available to the researcher**



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Reminders Other Support:

- This includes but is not limited to:
 - All Senior/Key Personnel
 - Required for all individuals designated in an application as senior/key personnel
- Do not include:
 - Start up packages
 - Training awards and *prizes*
 - Gifts:
 - Item or service with expectation of associated time commitment is **not** a gift
 - It's an in-kind contribution and must be reported as Other Support

Reminders Other Support:

- **SciENcv template for Other Support**
 - Profile system for all who apply for, receive or are associated with research support via federal agencies
 - SciENcv is available in My NCBI

**For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED
PHS 398 OTHER SUPPORT**

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format shown below.

*Name of Individual:
Commons ID:

Other Support – Project/Proposal

*Title:

Major Goals:

*Status of Support:

Project Number:

Name of PD/PI:

*Source of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

* Total Award Amount (including Indirect Costs):

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [enter year 5]	

Name of Individual:

Commons ID:

IN-KIND

*Summary of In-Kind Contribution:

*Status of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period

Year (YYYY)	Person Months (##,##)
1. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [enter year 5]	

*Estimated Dollar Value of In-Kind Information:

***Overlap** (summarized for each individual):

|

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature: _____

Date: _____

Reminders:

- Excellent Score?
 - Notify the IRB, if human subjects involved
 - Animals
 - If you don't have an approved IACUC, let the IACUC know
- Do not list effort
- Key Personnel
 - “**PD/PI** and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.”
- Other Support required regardless of support
 - *If none, put none*



Immediate Notification of Undisclosed Other Support

- CASE: I just found out that the PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR
 - **Submit updated Other Support to SOM OG&C as soon as it becomes known**
 - **SOM OG&C will submit to NIH**
- NEW collaborations?
 - **After the grant is awarded**, requires prior approval by NIH
 - (Process: Consider comparable to a “change in scope”)

E-Signature

Permissible, but it must be “flattened” (capable of being printed)

“Print” as a PDF

(Jon will demo at the end)

FAQs: Other Support

<https://grants.nih.gov/faqs#/other-support-and-foreign-components.htm?anchor=alphaHeader4227>

Changes for Biosketches

- **Section A** now includes research support information (was previously in section D)
- **Section B Renamed** 'Positions, Scientific Appointments, and Honors'.
 - List in *reverse* chronological order
 - *All positions and scientific appointments both domestic and foreign,*
 - *Affiliations with foreign entities or governments*
 - *Including titled academic, professional, or institutional appointments **whether or not remuneration is received***
 - *Whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary)*
- **Section D.** Scholastic Performance **updated**
 - Remove 'Research Support'
 - Section D is solely present on the fellowship version of the Biosketch, and no longer includes research support, only Scholastic Performance



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BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*



INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY

**A. Personal Statement****B. Positions, Scientific Appointments, and Honors *(new title)***

C. Contributions to Science
5 ONLY
(4 publications each ONLY)

FAQs: Biosketches

<https://grants.nih.gov/faqs#/biosketches.htm?anchor=alphaHeader4029>

Additional Questions

medres@case.edu

Subject line: training question

Foreign Component Details, if needed by Speakers

Additional info on Foreign Component OS

- **All** available to the researcher
 - This includes but is not limited to, **financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc).**
 - Institutional resources, such as core facilities or shared equipment that are made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources.

This includes but is not limited to:

- **Resources and/or financial support from all foreign and domestic entities**
- **Consulting agreements**
 - When the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities. Non-research consulting activities are not Other Support.
- **In-kind contributions**
 - e.g. office/laboratory space, equipment, supplies, employees or students supported by an outside source.
 - If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, **the recipient must provide reasonable estimates.**
 - **Only resources UNIQUELY available to the researcher**

RPPR Errors Expanded Detail

Reporting effort

Manuscripts

- Must be compliant. Non compliant pubs delay award notice

Human subjects and/or animal use

- Don't contradict what was in the proposal regarding human subjects or animals are involved
- HSS (human subject inclusion) MUST be submitted in ASSIST PRIOR to the RPPR
- Ensure that you don't contradict what was in the proposal regarding human subjects or animals are involved

Questions G.9 and G.10 must be confirmed in SPARTA FP

- G.9 Unobligated balance
- G.10 Foreign Component (PI must confirm)

Reduction of effort for Key Personnel ?

- Effort reported should NOT be reduced more than 25%
- Foreign Component Question G.9 must be confirmed in FP BY PI !

Anything different to report?

- New foreign collaboration or inclusion of animals
- Articulate as a approval request
 - We would like to.....(not....we DID)

(Program Grants): Submit NIH's defined budget amount for future period

- Not usually relevant for R series
- Don't ask for more; don't ask for less
- No carry forward request in RPPR (NOGA YOGA per MRC)

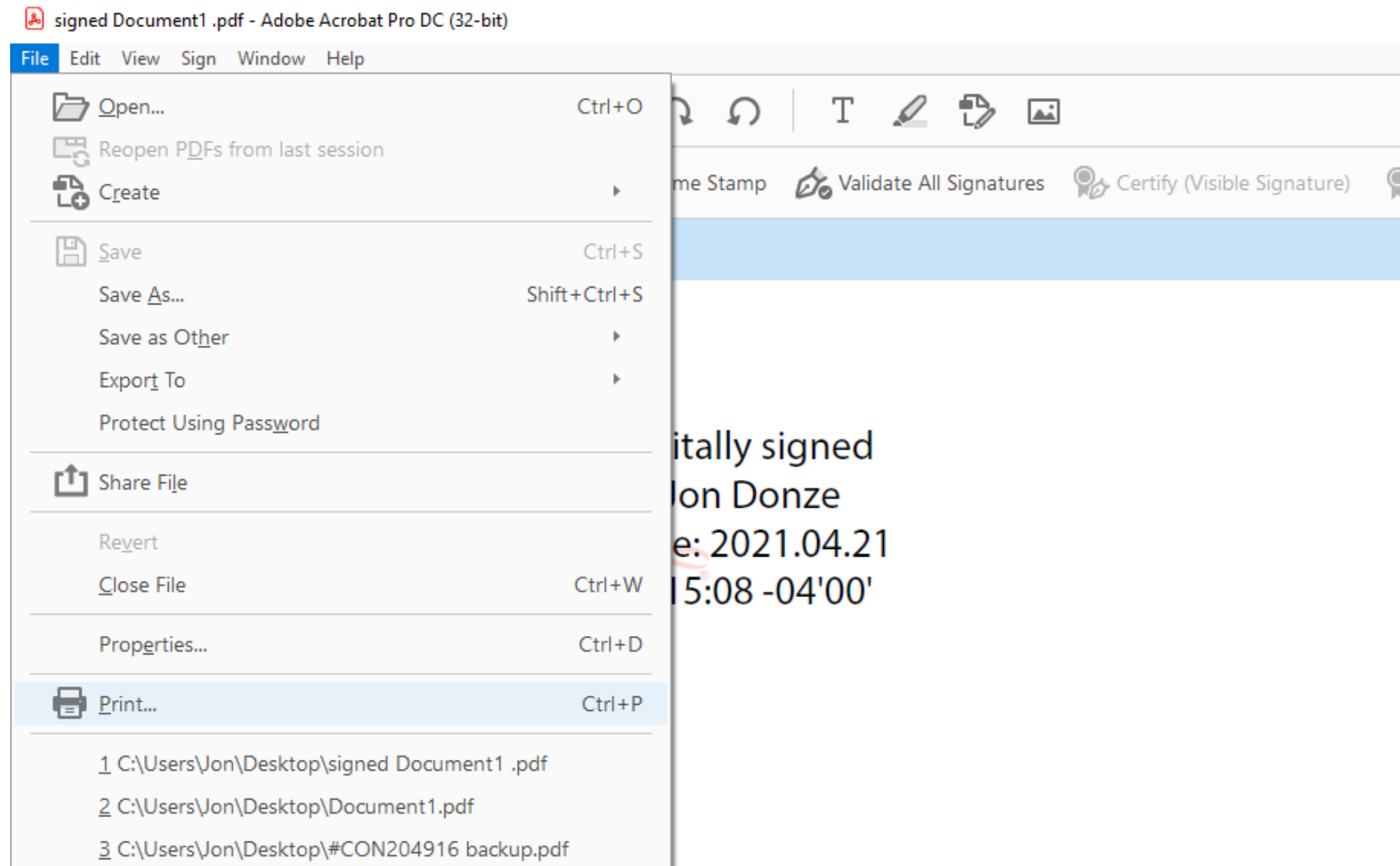
Demo: “Flattening a PDF”

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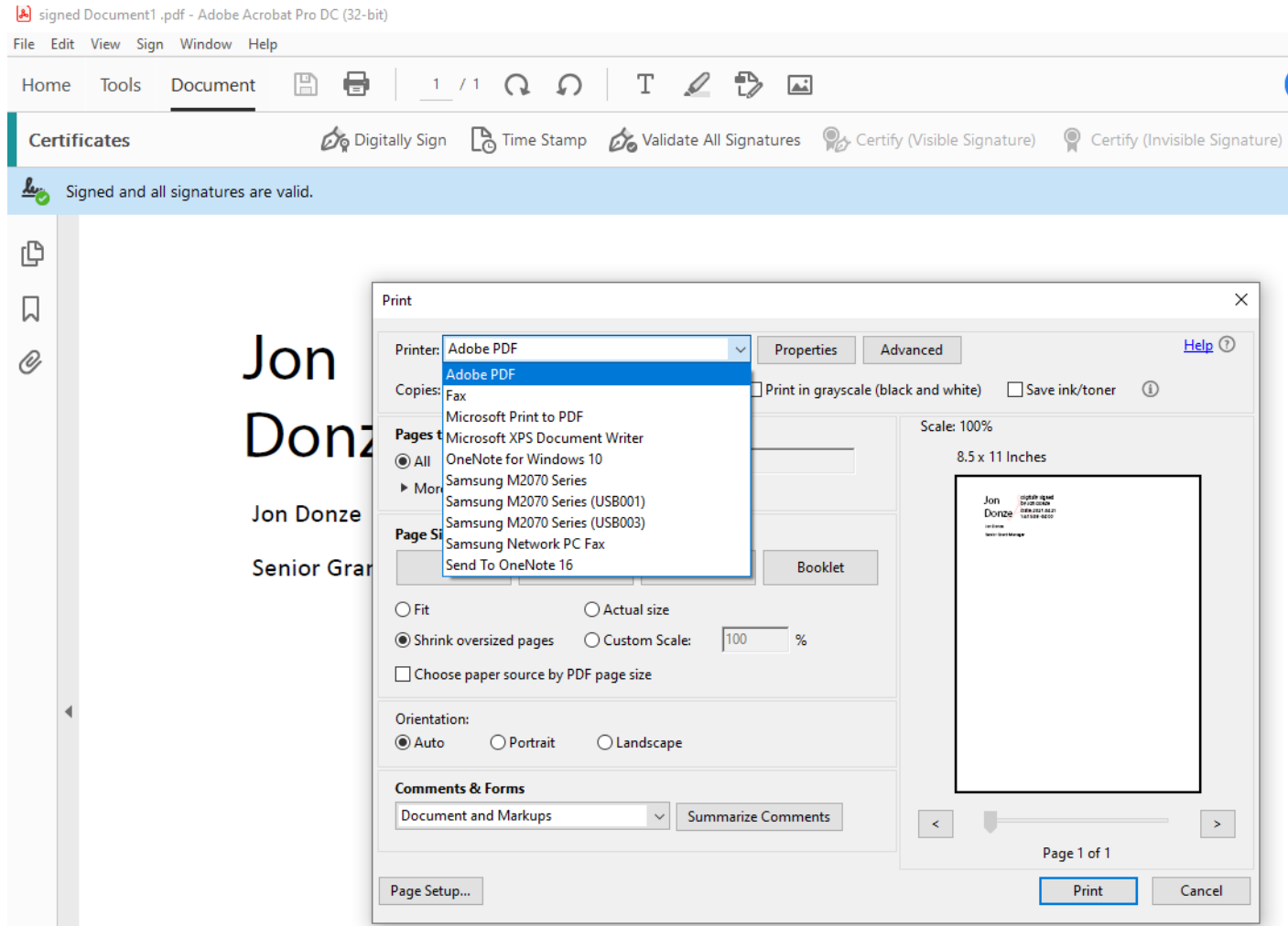
A digitally signed PDF can be recognized by the blue bar.



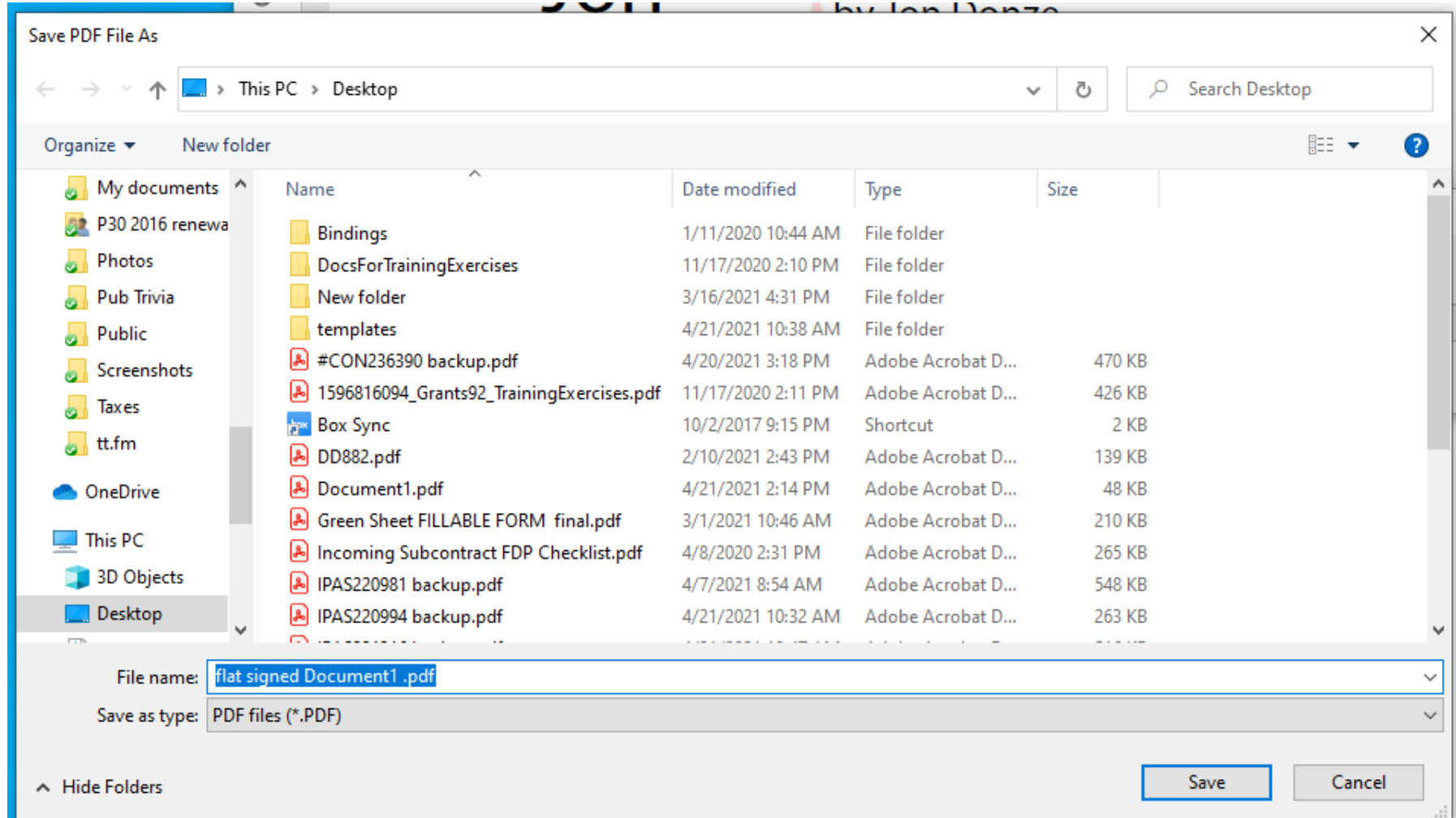
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Jon Donze

Senior Grant Manager