



**Federal Sponsor Other Support &
International Engagements Webinar
March 24, 2022**

Scenarios and Answers



SCENARIO 1

Dr. Chen from Fudan University in China has written a letter of support for Dr. Patel's R01 renewal. The letter states:

Dear Dr. Patel,

I write to confirm my enthusiastic support of your NIH R01 competing grant renewal application entitled Genetic and Molecular Analysis of Abhorrentius Deletrius. As you know, we recently determined that human cells containing a mutation in the RAD-123 line are severely compromised for human HeLa cells and XYZ- deficient hamster cells. We look forward to learning the results of your proposed experiments. Indeed, I think your experimental plan provides a logical path forward to test how interactions between RAD-123 and BAD-321 facilitate cellular retrotransposition. In sum, I find your project exciting and I look forward to our continued interactions and learning the results of your proposed studies.

*With best regards,
Dr. Li Chen*

***Does Dr. Patel need to include Dr. Chen's letter in her Other Support documents?
What if their roles were reversed?***

Dr. Patel does not need to include this letter of support from Dr. Chen in her Other Support document. It is a gesture of goodwill and intellectual interest. There is no actual support (monetary or in-kind) being provided by Dr. Chen toward any of Dr. Patel's research.

The same holds true if the roles were reversed.

**SCENARIO 2**

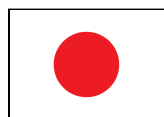
Dr. Patel is the PI on a clinical trial sponsored by GutenPharma in Germany. The contract can be found by going to AWD012345 in eRPM.

Does Dr. Patel need to include the GutenPharma trial in her Other Support document?

Yes. Dr. Patel does need to include this in the GutenPharma trial in her Other Support document because this is a research project she is actively working on.

If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the contract)?

No, she does not. Since there is an Award number in eRPM, we know that this agreement is through U-M and it's not with Dr. Patel personally.

**SCENARIO 3**

Dr. Patel has a visiting scholar, Dr. Sato from the University of Tokyo, working in her lab. Dr. Sato is contributing on two U-M internally funded research projects that Dr. Patel is currently working on. Dr. Sato is supported 100% by the University of Tokyo.

Does Dr. Patel need to include Dr. Sato in her Other Support document?

Yes, Dr. Patel does need to include Dr. Sato as a resource in her Other Support document. Since Dr. Sato is supporting Dr. Patel's research endeavors, Dr. Sato needs to be listed as a resource in Dr. Patel's Other Support. In this case, Dr. Sato would be considered an in-kind resource.

If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the contract)?

The answer is probably no. It really comes down to the language that NIH uses in the requirements for the Other Support supporting documentation. U-M's current interpretation of NIH's language is that a supporting document only needs to be included if the form of Other Support is in regard to the U-M investigator's appointment, affiliation, or employment at a non-US entity. In all likelihood, Dr. Patel would not need to include supporting documents for Dr. Sato, unless somehow Dr. Sato's presence in Dr. Patel's lab were a term or condition in an agreement that Dr. Patel has with the University of Tokyo.

For example, let's say that Dr. Patel has an honorary unpaid appointment with the University of Tokyo, and as part of that agreement they say, "We're going to send this fabulous researcher, Dr. Sato, to work in your lab for six months." Even though it's an honorary appointment, it's a term of that appointment, and in that case, yes, the agreement with the University of Tokyo would need to be included as a supporting document.

**SCENARIO 4**

Dr. Patel has a consulting agreement with DrogueFantastique in France. She's overseeing the protocol design of their upcoming clinical trial for a new drug.

Does Dr. Patel need to include the DrogueFantastique trial in her Other Support document?

Yes. It does need to be included in Dr. Patel's Other Support because the consulting includes the design, conduct, or reporting of research.

If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the contract)?

It depends. If the consulting agreement is with Dr. Patel personally (outside of her U-M role), then it would need to be included. However, there are situations where U-M investigators enter into consulting agreements that are routed through U-M. If that were the case here, then there would not need to be any supporting documentation because the agreement would be with the institution (U-M) and not with Dr. Patel.

**SCENARIO 5**

Dr. Patel has a consulting agreement with Pfizer. She's overseeing the protocol design of their upcoming clinical trial for a new drug.

Does Dr. Patel need to include the Pfizer trial in her Other Support document?

Yes, Dr. Patel does need to include this as an activity in her Other Support document because the consulting includes the design, conduct, or reporting of research.

If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the contract)?

No. If the agreement is with a U.S. entity, such as Pfizer, then NIH's new requirements for supporting documents do not apply. They only apply to entities outside of the U.S.

**SCENARIO 6**

Dr. Patel has a Dutch doctoral student, Bram Meijer, working in her lab on his dissertation. He's making use of Dr. Patel's facilities, equipment, supplies, personnel, etc. Bram is supported 100% by the University of Amsterdam.

Does Dr. Patel need to include Bram on her Other Support document?

Dr. Patel does not need to include Bram as an Other Support resource in her document. Bram is working on his dissertation and not providing any sort of support to Dr. Patel's research endeavors. This is probably the type of situation where you would actually want to make sure you had all of the necessary information from the investigator. As the scenario is written here and unless we had some additional information, Bram is not a source of support to Dr. Patel's research endeavor, so he would not need to be listed. *If* Bram were contributing in some way to any of Dr. Patel's research endeavors, then he would need to be included as an in-kind resource on her Other Support document.

If yes, does she need to provide "Supporting Documents" to NIH with her Other Support (e.g., an English-language copy of the contract)?

No. Bram is not included as an Other Support resource and is not contributing to any of Dr. Patel's research endeavors.