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Technology Transfer Case Study: *The Researcher - Inventor Relationship: When a Study Depends on Another Party's Invention*

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Contents

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Introduction

Researchers are increasingly being challenged to find ways to ensure their research findings can be translated into practice on construction sites (research to practice or r2p). A study that is dependent on an intervention owned or controlled by someone other than the researcher or the research institution, such as an inventor, can create a new set of challenges that safety and health researchers may not have encountered before. For many investigators the business aspect of working with an inventor is new territory.

This case study offers important lessons to help researchers identify and mitigate or prevent potential problems that can arise when an inventor controls access to the equipment or product needed for the successful completion of a research study.

Background

In this case study, two research studies were funded to evaluate the ergonomic benefits of a new piece of equipment developed by an outside inventor. The new equipment was brought to the researchers' attention by another researcher and the funding agency. Representatives of these groups along with the inventor asked the researchers to evaluate whether this new equipment would, as hoped, reduce the risk for back, shoulder and other musculoskeletal injuries.

The research team initially received funds for a pilot study of the new equipment. When the pilot study was successfully completed, the researchers submitted a proposal and received funds to do a follow-up study to assess changes to the equipment as well as the potential for it to reduce respiratory health risks identified during the pilot study.

The success of both studies relied on the inventor, who was also the manufacturer and owner, making the equipment available to the researchers in a timely manner for testing.

Study #1: Pilot

The first study was a one-year pilot to explore the effects of a new piece of equipment on back and shoulder muscle effort and on back postures. The researchers' goal was to quantify and compare exposures to physical risk factors between use of convention equipment and the new equipment. Each participant used the conventional equipment for a half day and the new equipment supplied by the inventor for the other half of the same day. Workers using traditional equipment perform their work in a stooped posture, using the equipment to support their body weight, and demonstrating little shoulder muscle activity. In contrast, the new equipment was designed to allow workers to spend more time upright and less time bent over at the waist, exposed to extreme trunk flexion.

The proposal for the pilot study included a letter of support from the inventor on his company's letterhead stating: *"I am the inventor of this system… I am anxious to do anything I can to help you study our unique system… It is our sincere desire to help you in any way that we can…."* The new equipment (i.e., the invention or the intellectual property (IP)) was wholly owned by the inventor, and when the pilot project began the inventor had a patent application pending. Neither the researchers nor their university had any ownership share in the device. (To learn more about the patent process see the CPWR *Intellectual Property Patent & Licensing Guide for Construction Safety & Health Researchers and Inventors* (http://www.cpwr.com/publications/intellectual-property-patent-licensing-guide-construction-safety-health-researchers)).

The inventor provided the equipment for testing as needed, allowing the researchers to complete the pilot study on schedule, and the results of the pilot study were published in an article in a peer-reviewed journal. According to the study's findings, the new equipment improved posture and reduced exposure to extreme trunk flexion, but *"resulted in less desirable upper trapezius muscle activity."* These findings raised an important question as to whether the potential benefits that resulted from reduced trunk inclination angles outweighed the potential risks resulting from less desirable upper trapezius electromyography (EMG). The researchers concluded that this empirical question should be evaluated by study of musculoskeletal outcomes among workers using both systems for an extended period. They recommended that continued

development of the new equipment focus on: 1) minimizing the forces required to operate the equipment, and 2) increasing the production capability to encourage adoption of the system.

The research team briefed the inventor regarding the final report on the pilot study and the journal article describing the results. During these briefings, the researchers discussed possible design changes the inventor had proposed to achieve the desired ergonomic benefits, but they did not make specific design recommendations. They also noted that a secondary benefit of the equipment could be a reduction in workers' exposure to hazardous fumes produced by the work task, and recommended that any future research efforts include an assessment of these exposures.

The first project was considered a success due to the findings and the cooperative working relationship between the researchers and the inventor.

Study #2: Follow-up Study

Shortly after the completion of the pilot study, the research team approached the inventor to discuss the possibility of working together on a follow-up study to assess the changes the inventor said he planned to make to the equipment based on the pilot study's findings and to explore the potential reduction in exposure to hazardous fumes. The inventor agreed to participate, and engaged in frequent telephone conversations and emails with the researchers as the study proposal was being developed. The inventor and researchers discussed the changes being made to the equipment and the timing of when the next generation of the equipment would be available for testing.

The goals of the second study, as stated in the proposal, were to evaluate whether a new commercially-available piece of equipment reduces exposures to physical risk factors for work-related musculoskeletal disorders and to characterize fume exposures. The study called for collecting data in the field and expanding the scope of the study in terms of the number of participants, types of tasks, and control methodologies. The success of this follow-up study hinged on the inventor supplying the researchers with equipment that reflected design changes based on the findings from the pilot study, and doing so based on the schedule outlined in the

proposal. The proposal timeline included field testing, data collection, and analysis to begin within two to three months of the project's start date.

Just as they had done in developing the proposal for the pilot study, the researchers gave the inventor the opportunity to review and comment on the proposal prior to submission for funding. For this second study, the inventor's letter of support stated "*As you know, we have been developing several improvements to the system since your previous study....,"* and listed specific changes that *"we are incorporating… into the latest design of the system and may have more changes as we go… We understand that your proposal seeks to examine the effect of the [equipment] on exposures to both ergonomic risk factors and… fumes. As the manufacturer of the system, we certainly see value in your research… At the appropriate time, we will work with you to identify contractors familiar with the system for potential data collection opportunities."* The research project moved forward based on this letter of support and a verbal commitment from the inventor to provide the researchers with the redesigned version of the equipment so that testing could begin on schedule. The only formal relationship or agreement between the parties was predicated on the inventor's letter of support. There was no other written agreement in place between the inventor and the researchers that identified specific commitments, such as the version of equipment that would be used, when it would be delivered to the researchers, or how problems would be addressed.

Within 24 hours of being awarded funds for the second study, the research team notified the inventor by telephone and email that the proposal had been funded and laid out the timeline for when work would begin. The inventor offered no indication that the timeline could not be met. Even though the researchers were in regular phone contact with the inventor during the three month window leading up to when they were supposed to begin data collection, it was not until shortly before this first deadline that the inventor informed the researchers that the design changes were still underway. The inventor indicated that more time was needed to complete the design changes and that he would want to evaluate the changes prior to field data collection. Consequently, the researchers delayed the data collection start date for roughly two months. One month before the new data collection start date, the researchers received an email from the inventor indicating the design changes were on schedule. During this time period, the inventor

completed some planned changes to the system and brought a pre-production prototype to the researchers so that they could evaluate the changes being made prior to field data collection. As the new start date for data collection approached, the researchers learned that the equipment was still in the fabrication stage and the inventor would not have it ready. The researchers continuously reached out to the inventor through phone calls and emails about the status of the equipment and to try to establish a firm date when it would be available for testing. Roughly eight months after the second data collection start date was missed, the inventor informed the researchers that the equipment would not be made available for the study until additional internal testing of the redesign was completed. The researchers notified the funding agency that due to these delays they would not be able to fulfill the first year's study requirements.

In a conference call between the research team, the funding agency, and the inventor, the inventor expressed concern that if field testing produced unfavorable results related to productivity, which was not a focus of the study, their ability to raise the capital necessary to further develop and market their equipment could be negatively impacted. Based on this conversation, the scope of the project was modified. The researchers agreed to forgo the field evaluation, and evaluate the equipment in a university testing facility under controlled conditions with workers experienced with using traditional equipment. In turn, the inventor committed to providing the equipment to the researchers within two months. The inventor missed this deadline and subsequently withdrew support for the project citing financial hardship.

The researchers made another attempt to work with the inventor by asking if they could lease the equipment and received information back on what the inventor would charge. The researcher team followed up explaining that the inventor would have to sign a lease agreement with the university and obtain liability insurance. This latter requirement was part of the university's regular procedure for leasing equipment. The researchers then notified the funding agency and requested permission to use a portion of the project's funds to lease the equipment from the inventor. At the same time, the research team notified their university's purchasing department, which would be responsible for executing the lease arrangements between the university and the inventor. Once the researchers received approval from the funding agency to lease the equipment, the university's purchasing department sent the formal lease agreement and the

liability insurance requirements to the inventor. Shortly after, the inventor sent an email to the researchers formally withdrawing from the project.

To salvage the project, the research team designed and fabricated a prototype of the equipment that would allow them to complete some, but not all, of the research objectives. The in-house design allowed the researchers to compare the differences between fume exposures using their prototype and traditional equipment, and to also evaluate some ergonomic exposures. However, limitations with the design of the prototype developed by the researchers prevented it from being used for field testing.

Although the researchers did not achieve all of the goals in the proposal, they were able to document reductions in both physical demands and respiratory exposures using equipment that allowed workers to remain upright instead of bent over the task.

Lessons Learned

There are important lessons learned from this project that can be applied to future research initiatives that rely on equipment being voluntarily supplied by another party, such as an inventor or a manufacturer, for the successful completion of a research study.

Lesson 1: Address Ownership Issues Up Front

Intellectual property (IP) laws provide inventors/owners with the power to enforce their property rights in civil court and to sue for damages when unauthorized use or misuse of their invention occurs. When a research study relies on a third party's invention or property, ownership issues can arise. (See CPWR's *Intellectual Property Patent & Licensing Guide for Construction Safety & Health Researchers and Inventions*, *Section VI: Ownership: Who Will Own Any Intellectual Property Developed Under My Agreement?*).

Ownership issues can have a chilling effect on the relationship between an inventor and a researcher. This is especially the case if the ownership of the invention (the IP) has not yet been formalized through the issuance of a patent. An inventor may want to learn from a research

study, but may be concerned that a researcher will claim to be a co-inventor if design modifications identified by the researcher are incorporated into the invention.
It is important that anytime a researcher partners or collaborates with an inventor that ownership issues be addressed and documented in writing in the pre-planning or conceptual stage of a project.

As part of the process and to protect all parties, an inventor may want the researcher to formalize and execute certain agreements. These documents could include, for example, an invention disclosure form, a non-disclosure agreement, a contract for technical services, or a non-compete agreement, depending on the relationship between the parties. When a university is involved, the researcher should seek guidance from its technology transfer office. (See CPWR's *Intellectual Property Patent & Licensing Guide for Construction Safety & Health Researchers and Inventors Appendix A: Links to Examples of University Intellectual Property and Technology Transfer Policies; Appendix B: Sample Invention Disclosure Form; and Appendix C: Sample Non-Disclosure Agreement*.)

In this case study, the inventor had a patent pending for the equipment. Discussions about ownership in the pre-planning stage could have uncovered any concerns the inventor may have had about how the study could impact the patent process. It could have also provided the researchers with an opportunity to address these concerns through, for example, a written agreement that no attempt would be made to be listed as a co-inventor or owner of the equipment.

Lesson 2: Define Expectations and Verify They Can Be Met

For a project to be successful, each party involved needs to be able to verify that the other parties are doing their part. This is particularly important when a key participant in a project is voluntarily contributing time and/or equipment, or when their motivation for participating in the study may differ from that of the researcher.

Although a safety and health researcher and an inventor may share a common goal -- to develop or promote an effective intervention -- their motives may be very different. A researcher may be

motivated by the prospect of publishing the study results or determining the extent to which an existing piece of equipment effectively addresses a hazard, while an inventor's motivation for participating may be driven by how the research could be used to further efforts to market and sell their invention. What motivates the researcher will influence their expectations for the inventor and vice-versa.

It is important at the outset, when the project is still in the conceptual stage, to explore each party's needs and expectations. Both the researcher and inventor should have a clear understanding of the proposed study's time frame and what is expected to occur, what specifically each party can and will contribute to the study, and how and when the research findings will be used.

In this case study, the researchers' expectation was that the inventor would provide a redesigned version of the original equipment for testing shortly after the project's start date. In retrospect, however, the letter of support did not explicitly state that the inventor would provide the equipment, when it would be provided, or if there would be a cost associated with its use. The letter only committed to *"work with [the researcher] to identify contractors familiar with the system for potential data collection opportunities."* In fact, it is unclear from the letter if the inventor's redesign efforts had been completed or would be completed in time for the project. The letter states that the inventor is *"incorporating [changes]… into the latest design of the system and may have more changes as we go."* Furthermore, it is not clear in the letter or the proposal if the researchers required a redesigned version for the second study. The proposal only states that a new commercially available piece of equipment would be studied.

Given the researchers' past successful working relationship with the inventor and the inclusion of the inventor in the preparation and review of both proposals, it was not unreasonable to accept the letter of support for the second study as an indication of the inventor's understanding of what would be involved and willingness to provide the equipment in a timely manner. However, since the study's success relied on having access to equipment controlled by the inventor, the challenges encountered might have been avoided if, in the conceptual stage of the second project, the researchers and inventor had discussed and documented their expectations, including:

1) the version of the equipment that would be needed for the study,

2) when the equipment would be delivered to the researchers for testing, and

3) how and when the testing results would be used.

Such a discussion could have revealed potential barriers to accessing the equipment, including production, funding and/or ownership (patent) issues.

It would have also been helpful at the pre-proposal stage to have taken steps to verify that the inventor could deliver the version of the equipment required for the study. This could have been done by conducting a front-end evaluation of the equipment. At that time, if modifications were still underway, the researchers and the inventor could have discussed the proposed study's timing and agreed on a way to verify that the equipment would be ready when needed, or the researchers and inventor could have agreed to revise the schedule or study approach.

The researchers might also have been able to identify potential barriers to accessing the invention if the inventor had been asked or required to include specific information in the letter of support. A September 2013 report[1] from the National Institute for Occupational Safety and Health's (NIOSH) Board of Scientific Counselors Work Group on "Structuring Labor-Management Participation in Research Partnerships" found that:

> *"When NIOSH conducts field/intervention studies, typically an informal "letter of agreement" is prepared, prior to initiating the research, between the employer and NIOSH and submitted to the IRB. These letters are general in nature and are used to demonstrate the good intention of the employer to participate in the study. Other than showing a good intention to participate in the study, employers usually agree to nothing else. No specific details about the study are included in this letter and NIOSH has no criteria established for determining the minimum content of a letter of agreement."*

Based on this observation, a recommendation was made that:

[1] Report and Recommendations. Board of Scientific Counselors Work Group,"Structuring Labor-Management Participation in Research Partnerships: Request for Analysis and Recommendations," http://www.cdc.gov/niosh/BSC/pdfs/WorkGroupReport09182013FINAL.pdf, September 2013

"NIOSH should consider developing some general criteria or guidelines for minimum elements that must be contained in a letter of agreement beyond that of an employer demonstrating its good intention to participate in the study. The letter might contain some additional elements, such as stating that employee participation will be voluntary, employees can withdraw from participation at any time during the study without reprisal, and that confidentiality will be maintained. Other issues specific to the particular study being conducted could also be included in the letter."

This recommendation to have "minimum elements" included in letters of support could benefit research studies that rely on inventors or manufacturers. In this case example, had the inventor been asked to explicitly state in the letter of support what he would provide and when, potential barriers or concerns identified later, which led to delays and forced the researchers to redesign the study, might have been identified and addressed. For example, if the inventor was unwilling to include a timeframe for when the equipment would be delivered, that could have been an early indicator that the equipment might not be available when needed for the study.

Lesson 3: Reach an Agreement & Keep Written Records

Whether the relationship between the researcher and the inventor is termed a collaborative effort, joint venture, or strategic partnership, it is important to explore and define each party's obligations at the outset and put them in writing in a project plan or a formal agreement.
It is much easier to reach an agreement at the beginning, while energy and attention are on the nature of the new relationship and before there is an opportunity for misunderstandings to arise. The following are examples of items that can serve as the basis of a written agreement or plan between parties:

- Identification of the parties to the agreement or plan, including names, addresses, and other information as appropriate, such as state of incorporation and authorization to conduct business in the appropriate jurisdiction if business entities are involved;
- Determination of the type of relationship being created, e.g. partnership, joint venture or other relationship or form of organization;
- Description of the project to be undertaken, its scope, extent and duration;
- Contributions of each party, whether in money, property, time, skill, etc.;

- Timing of when each contribution must be made and the effect if any party fails to make its contribution;
- Timeline for completion of tasks by each party;
- Whether any type of non-disclosure or non-compete agreement should be put in place between the parties;
- Steps for terminating the relationship; and
- Effective date of agreement or plan.

In this case study, a written plan or agreement between the inventor and the researcher that clearly stated the inventor's commitment to supply a specific version of the equipment, the terms under which it would be supplied (e.g., free of charge, by a certain date), and how and when the research would be conducted and the findings made public could have brought to light any concerns the inventor may have had regarding, for example, obtaining financial backers, how the results would have been disclosed, and the pending patent, that may have led to the inventors withdrawal of support for the project.

Conclusion

When working with an inventor or manufacturer who owns the equipment or product required for the success of a research study, it is important for researchers to recognize that their business interests may take priority over the researchers' and the study's needs and goals. While there is always the risk that an inventor who is voluntarily providing equipment for a study may withdraw support, there are steps a researcher can take early on in the process – at the conceptual and proposal stages – to identify and address potential conflicts before the success of their research study is jeopardized:

1. Address ownership issues up front to avoid potential conflicts or resistance to sharing equipment at a critical point in the research process.
2. Hold a formal meeting with the inventor to establish expectations and agree on a mechanism to verify those expectations can and will be met.
3. Reach a written agreement on what will be provided, when it will be provided, how the research will take place, and when and how the results will be released and used by both

parties. At a minimum, ask the inventor to include this information in their letter of support.

Throughout the process, document all interactions and verbal agreements reached through meeting minutes, emails, and/or formal agreements, and share these documents with everyone involved in the project.

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