

## COURSE 13, TUTORIAL 1

### PART 1

# HUMAN SUBJECTS PROTECTION AND THE FINAL RULE



**A**s you progress from Phase I to Phase II and finally to Phase III, there are a variety of experimental methodologies you will employ during the development of your technology and its transformation into a commercializable product or service. In some cases, safety and/or efficacy testing may be required with human subjects and/or animals. In either of these cases, you will need to provide the sponsoring agency's SBIR/STTR office with documented additional safeguards showing that you and your subcontractors will provide the animal or human test subjects with protections provided by federal regulations, policies and guidance. Fortunately, there are standardized processes that you can follow to ensure that this happens. The purpose of this course is to address both human and animal test subject protection.

#### THE FINAL RULE

Starting January 19, 2018, all federally funded research and development programs that utilize human test subjects will be required to be compliant with Federal Policy for the Protection of Human Subjects, also known as the "Final Rule". The Final Rule is a unified policy adopted by all federal agencies, including those that provide SBIR/STTR funding. The name is derived from the original unified federal policy covering human test subject protections, adopted back in 1991 and last amended in 2005, known as the "Common Rule". The Final Rule, adopted January 19, 2017, codifies all human test subject protections for federally funded studies, including SBIR and STTR grants and contracts. Note that the Final Rule represents the minimum protections for human research subjects. Each agency may impose additional policies to protect human test subjects. These rules can be found in the agencies' SBIR/STTR Funding Opportunity An-

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nouncements or on their websites. Links to each SBIR/STTR granting agency's human test subject protections can be found in the Useful Links section of this tutorial. You will need to know what is covered by the Final Rule to ensure funding of your SBIR or STTR proposal. The legal language of the Final Rule will be exactly the same from agency to agency. It truly is one rule for all.

#### APPLICATIONS OF THE FINAL RULE

The Final Rule "applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropri-



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ate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards or IRBs reviewing research that is subject to this policy, must comply with this policy.” There are subparts to the Final Rule that provide specific protections to pregnant women, human fetuses, neonates, prisoners and children. There are also some types of human subject research that are exempt from the final rule. We will discuss these later.

As is the case with all federal policies and regulations, definitions are the key to understanding exactly what they cover and how they apply to you. To determine if your research is subject to the human subject protection regulations in the Final Rule, you would want to know: What is a human subject?; What is research?; and Is all human subject research subject to the Final Rule?

The Final Rule defines a human subject as a living individual about whom an investigator, whether professional or student, is conducting research:

- » Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- » Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

### **INTERVENTION VS. INTERACTION**

You will notice that the Final Rule further defines investigator actions with a human subject as intervention or interaction. These terms have specific meaning in the Final Rule. **Intervention** is defined as including “both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.” **Interaction** is defined as including “communication or interpersonal contact between investigator and subject.” These are very broad definitions designed to cover almost all investigator/human subject interac-

tions. If, as an investigator, you are studying living humans or their tissue, it is likely that your research will fall under the regulatory auspices of the Final Rule.

### **DEFINING RESEARCH**

The Final Rule defines research as “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.”<sup>1</sup>

For purposes of the Final Rule, these activities are deemed not to be considered research:

- » Scholarly and journalistic activities, including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- » Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health.
- » Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- » Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

<sup>1</sup> Federal Policy for the Protection of Human Subjects – Final Rule, Federal Register /Vol. 82, No. 12/Thursday, January 19, 2017. pp 7260-7261. <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf>