



FLORIDA STATE
UNIVERSITY

Human Subjects Research: COVID Town Hall

T. Howard Stone, JD, LLM, CIP, Director
Office for Human Subjects Protection
FSU Office of Research



FSU and Researchers Human Research Responsibilities

IAW federal law, FSU and its researchers will comply with all applicable requirements to protect human research subjects, including minimizing risks to subjects and others.

The FSU Office for Human Subjects Protection (OHSP) and the Institutional Review Board (IRB) implement and enforce the applicable requirements.



COVID-19 present unprecedented risks to study subjects and others



- Uneven prevention measures
- Poorly understood risk and protective factors, including exposure and transmission
- Deficient, ambiguous testing and testing protocols
- No vaccine
- Lack of accepted treatment
- Health systems, among others, are unprepared and overwhelmed



Notwithstanding city, county, state and FSU institutional policies, the FSU IRB and OHSP are required by federal law to take steps to ensure that human subjects are protected against risks, including COVID-19.



What Have We Done?

1. **Halted** current *in-person* interactions and interventions involving research subjects; see—
<https://news.fsu.edu/announcements/covid-19/2020/03/23/temporary-cessation-to-some-fsu-human-subjects-research/>
 - ✓ Exceptions apply (next slide)
2. **Posted** online COVID-19-related guidance and resources
 - ✓ <https://www.research.fsu.edu/research-offices/ohsp/>
 - ✓ FAQs
 - ✓ Links to federal guidance
3. **Provided** RAMP IRB COVID-19-related SOP, templates, worksheets, forms



What More Will We Do?

1. Identify exceptions

- ✓ Studies involving remote interactions or interventions that don't compromise human subject safety;
- ✓ Studies with substantial likelihood of therapeutic benefit for individual human research participants;
- ✓ Clinical trials where all in-person interactions and interventions occur only within a clinical care context; related activities that can be done remotely must be done that way; or,
- ✓ Diagnosis, treatment, interventions, or other research activities directly focused on COVID-19 or Coronavirus Disease.



What More Will We Do (cont'd)?

2. **Maintain** human research oversight of current studies (i.e., protecting human research subjects)
3. **Prioritize** IRB review of study modifications to substitute remote for in-person activities; new, excepted studies
4. **Continue** review of newly-submitted modifications and studies unrelated to COVID-19, with appropriate conditional approval of in-person activities.



QUESTIONS & DISCUSSION

CONTACT INFORMATION:

T. Howard Stone, JD, LLM, CIP

Director, Office for Human Subjects Protection

thstone@fsu.edu

OHSP Main: 850-644-7900

OHSP email: humansubjects@fsu.edu