

SARS-Cov-2, the Law and You:

How COVID-19 Laws and Regulations Affect Small Clinical Research Sites

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May 7, 2020



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Learning Objectives

- Describe new and existing legislation designed to protect American workers and aid small businesses, including financial assistance and changes to SBA requirements;
- Discuss the changing regulatory landscape and ways your clinical research site can pivot in operations and conducting clinical trials safely and in compliance with regulatory agencies like FDA, IRB, etc.;
- List key actions that clinical research sites needing urgent assistance in financial and regulatory matters must take to stay afloat during COVID-19.

Financial Considerations



- Only you can decide which trials make the most safety, treatment, and financial sense to proceed... but once you do, consider what needs to be documented:
 - Home health
 - In-home
 - Your staff?
 - Contract?
 - Local
 - Telehealth

Financial Considerations

- Home health
 - Vetting
 - State specific
 - Logistical considerations such as onboarding study personnel, training, IRB/FDA documentation
 - SOPs should be 'in play' to address...

(SOP Advice: should be training, workflow, and compliance device all in one)

Financial Considerations

- Home health
 - SOPs should be 'in play' to address:
 - Equipment
 - Transportation
 - Safety precautions
 - Lab/testing sites
 - Sponsor & Regulatory communication, steps
 - Data Collection
 - Documentation

Financial Considerations



- Telehealth
 - One version to another VS none to some
 - Still costs and has compliance requirements
 - Again, SOPs should address:
 - Platform
 - Security & Privacy
 - Who & Where
 - Scope of Qualifying Visits
 - Sponsor & Regulatory Communications, Steps
 - Data Collection
 - Documentation

Financial Considerations... Regulatory

- **No matter the modality**

- Study modification approval required IN ADVANCE UNLESS AN EMERGENCY
 - Study documentation required
 - NTF
 - General Capture of timeline & events
 - Audit Trail
 - SOP alterations

Financial Considerations... Regulatory

- First, is this an emergency situation?
 - If so, the regulations allow for this ALREADY!
 - And, could it now be an emergency?:
 - <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>
 - <https://www.fda.gov/news-events/fda-newsroom/press-announcements?page=0>

Financial Considerations... Regulatory



- It it's not an emergency, then it's time to pull together your plan
 - Safety restrictions to facility and for remote working
 - Emergency Preparedness
- Flexibility here (HINT: It has always existed)
 - YOU dictate your protocol, not these agencies
 - Standard of care has changed!
 - Examples
 - FDA notices in several areas
 - Ship product directly to subjects
 - Employ local testing and lab facilities that patients can seek and coordinate instead of on-site visits

Financial Considerations... Regulatory

- Flexibility here
 - And, of course, RE-CONSENT:
 - You do need to document that you have discussed the new procedures and protocol changes, along with all of their impacts, with each research subject, and made it clear they have the right to refuse, and discussed also what that would look like.
 - De Facto – you have to in fact have a plan for all that, and for how you'll convey, provide response time, and keep the process as close to normal as possible, plus document.
 - Don't forget modalities like expedited reviews, short form consents, and that steps like training staff on new steps must be included and considered.

Financial Considerations... Regulatory

- Flexibility here
 - Just have to show the plan is well constructed and safety is paramount, along with data integrity
- Submit to FDA, IRB, etc.
 - Consult and communicate NOW & THROUGHOUT & AFTER
 - Include the initial safety steps already taken as a part of this package
- Then circle back to Sponsor again with same communications, if you haven't already

Financial Considerations... Contracts

- And now for contracts...
 - Increased cost and time to address:
 - Screen failing of subjects related to holds/shelter in place orders
 - New IP delivery channels
 - Enhanced pre-screening of potential subjects by tele-health
 - PPE and increased sanitation requirements
 - Pivoting technology and software for remote monitoring, other remote modalities

Financial Considerations... Contracts

- Approach the sponsor *with* knowledge and *without* fear!
 - Knowing your contract and what to look for in it
 - Non-adversarial, but may have to escalate
 - What are your exact needs? The 'ask' must be defined
 - Have items to offer, like amendment date mechanisms

Financial Considerations... Contracts

- Start with anecdotal and move toward data
 - Use the FDA daily guidance, other announcements from regulatory authorities like IRB
- Force Majeure
 - If you have to go there...
 - Labor disruption
 - Public Health Crisis/Emergency/Pandemic
 - 'Act of God'
 - Unforeseeable

Financial Considerations... Contracts

- Plan for Unanticipated Expenses
 - Learn from this time – have your ‘petty cash’ negotiated
 - Draft long-term and broad SOPs
 - Clarify certain sections, like force majeure, in future negotiations

“Small” Business Learning Objectives

- Employer Requirements
 - OSHA
 - COVID Paid Leave
 - EEOC
 - Medical Information
 - Hiring
 - Reasonable Accommodation
 - Harassment
- Small Business Assistance
 - Payroll Protection Program
 - Economic Injury Disaster Loans/Bridge Loans
 - Federal Reserve Main Street Loans
 - Payroll Tax Credits
 - Debt Relief Programs
- Small Business Resources

OSHA

- Safety requirements related specifically to SARS-COV-2 are different by State
- Provision of PPE is required to the level needed for the job (gloves, masks, etc.)
- Office needs to follow proper social distancing protocol



Families First Coronavirus Response Act – Paid Leave

- **Sick Leave:** FIRST two weeks of paid leave given to anyone who can't work b/c of quarantine or has/is waiting for a diagnosis of COVID-19
- **Family Leave:** FIRST two weeks of paid leave at 2/3 the rate for someone who needs to care for someone who is quarantined or schools closed
 - 10 weeks of 2/3 paid leave for any employee who can't b/c schools are closed **(Total of 12 weeks)**
 - **Exception:** Undue hardship that might jeopardize the business
- Full time employees (40 hours of leave per week), part time employees (avg hours)

Families First Coronavirus Response Act – Tax Credits

- **Reductions:** Can pay this by reducing from payroll taxes up to the payment cap (\$511 per day)
- **Amounts:** Up to \$511 per day, which includes health care coverage for those employees.
 - Up to \$200 per day for the extended leave.
- **You can't receive both the tax credit for the PTO and the loan forgiveness for the same time period**
- **Exemption:** Some health care providers and emergency responders might be exempted from the Sick/Family Leave requirement

EEO – Medical Information/Entering the Workplace

- **Testing/Attendance**

- You can ask if someone is experiencing any symptoms suggested by the CDC, and send them home if they refuse to answer
- Can check employees' temperature at the door
- Can tell an employee to go home if they have symptoms
- Can require a Doctor's note to come back

- **Information Sharing**

- Information must be kept private
 - Separate from their personnel file
- Employer can tell a public health agency if they test positive
- Employees are allowed to report another employee who has symptoms

EEO – New Hire Requirements

- You can screen an employee for COVID for contingent hire
 - You must screen all employees in the same role
- You can delay the start date of an employee who has COVID symptoms
- You can withdraw a contingent offeror symptoms
 - If an employee is needed to start immediately (do so with caution)



EEO – Reasonable Accommodations/Harassment

- **Higher risk workers** request accommodations – try to take precautions that don't cause an undue burden (separation, plexiglass, etc.).
 - Consider temporary removal of marginal duties or temporary transfer to a different position
- **Mental Conditions:** Must work to determine whether accommodation is needed or would help.
- **Telework Accommodations:** Some workers need additional reasonable accommodations for work from home than they have in an office.
 - Don't need to allow telework just b/c they are in a high-risk group
- **Risk Group Exclusion:** You cannot exclude someone (or not hire) b/c they are over 65 or are in a risk group and you don't want to give accommodations
- **Harassment:** *Be mindful of potential harassment on the basis of gender, race or another characteristic being more likely to have COVID*

CARES Act – Payroll Protection Program

- **Purpose:** To incentivize small business to keep their staff on payroll
- **Eligibility:** Small businesses under 500 employees
- **Structure:** Loan at a 1% interest, 2 years to pay back (six-month deferment)
- **Amount:** Up to 2.5x monthly EMPLOYEE payroll (including benefits up to \$100k annual salary), maximum \$10M
- **Forgiveness:** If employees are kept on payroll through June 2020 (or for 8 weeks), 75% of expenses are spent on payroll
 - Can immediately rehire employees who were let go and keep for 8 weeks
- **Allowable Uses:** Rent or Mortgage, taxes, benefits, electricity, gas, water, internet
 - All employees covered must be US permanent residents, located in the US
- **Deadline:** Available until June 30, 2020 or when funding runs out
- **Restrictions/Exclusions:**
 - You must pay employer/employee taxes
 - Family and Sick Leave under Families First Act
 - If EIDL is used, you may only use PPP to refinance EIDL

Payroll Protection Program Application

- **Application Process:**

- Applications are ONLINE, through any SBA 7(a) lender (most banks require you to have an account)
- Submit proof of US residency
- Need to submit proof of payroll – Payroll processor records, 1099-Misc, payroll tax filings
- ICs/Sole Proprietors – Income Statements, Bank Records
- **Forgiveness Application** within 12 weeks of receipt of funds

- **Certifications:**

- Spend the money properly
- Company existed before February 15, 2020,
- No delinquent SBA or other federal loans,
- No owner of 20% or more is incarcerated
- Current economic conditions make this loan necessary to continue operations

Economic Injury Disaster Loans

- **Amount:** Up to \$2M
 - Up to \$200k approved w/o personal guarantee
 - Up to \$25k w/o collateral
- **Interest:** 3.75% (2.75% for nonprofits)
- **Restrictions:**
 - Need to pay employees or other operations expenses
 - No dividends or refinancing
- **Loan Advance**
 - \$1,000 per employee up to \$10k
 - Paid before loan proceeds
 - Doesn't need to be paid back
- **Bridge Loan** – up to \$25k available while waiting for a response



Federal Reserve Main Street Loans



- **Amount:**
 - \$1M to \$25M for new loans
 - \$1M to \$150M for expanded loans
 - Maximum of 4x EBITDA
- **Interest:**
 - 250 to 400 basis points over prime
 - Amortization is deferred for one year
- **Eligibility:** Up to 10,000 employees
- **Restrictions**
 - Executives to freeze compensation
 - "Haircuts" for compensation over \$425k
- **Lender:** Any Lender (Federal Reserve, not SBA)

Comparing Loan Programs

	PPP	EIDL	Main Street
Amount	2.5x Payroll + Benefits Up to \$10M	Up to \$2M Up to \$25k w/o collateral Up to \$200k w/o personal guarantee	Maximum 4x EBITDA \$1M to \$25M new loans \$1M to \$150M expanded loans
Eligibility	Under 500 Employees	Under 500 Employees	Up to 10,000 employees
Interest	1% per year	3.75% (2.75% nonprofits)	250 to 400 basis points over prime
Forgiveness	All	\$10,000 advance (\$1,000 per employee) is forgiven	None Amortization is deferred one year
Restrictions	Payroll – 75% Rent/Mortgage Interest Utilities (No Sick Leave) Must Keep or Rehire Employees	Need to pay employees or other operations No refinancing or dividends	Executives to freeze compensation Compensation over \$425k gets a “haircut”
Government Sponsor	SBA	SBA	Federal Reserve

CARES Act - Tax Credits

Amount

- Up to 50% of wages paid (including healthcare) – up to \$10,000 per employee (\$5,000 credit)
- >100 Employees - Only those who were not working
- <100 Employees – All employees

Restrictions

- A full or partial closure of operations ordered by government
- Any calendar quarter in which revenues are less than 50% of the same quarter in 2019
- **Not eligible if you received a PPP Loan and Tax Credit Wages under Families First are not allowed**

Timing

- Starts either March 12, 2020 or the first calendar quarter with 50% loss of revenue from 2019
- Ends the end of a quarter where revenue tops 80% of 2019 or December 31, 2020

Structure

- Payroll Taxes are withheld
- If Payroll Taxes are not enough, a payment can be requested

Claiming

- Retain your taxes and report wages on your Form 941
- Credit is taken against Social Security Tax

Social Security Tax Deferral

- Social Security payments due from March 12-December 31, 2020 can be delayed
 - 50% due 12/31/2021
 - 50% due 12/31/2022
- Not eligible if you received a PPP loan
- **All businesses are eligible**



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SBA Debt Relief Program

Existing Microloans

- SBA is **automatically** paying the principal and interest of existing SBA **microloans** for 6 months

New Microloans

- SBA will **automatically** pay the principal and interest of new SBA microloans before September 27, 2020

Disaster Loans

- Automatic Deferments to December 31, 2020



Employer Resources



- **Employer Pandemic Preparedness -**
<https://www.eeoc.gov/facts/pandemic-flu.html>
- **Small Business Toolkit -**
<https://www.uschamber.com/co/start/strategy/small-business-resources-for-surviving-coronavirus>

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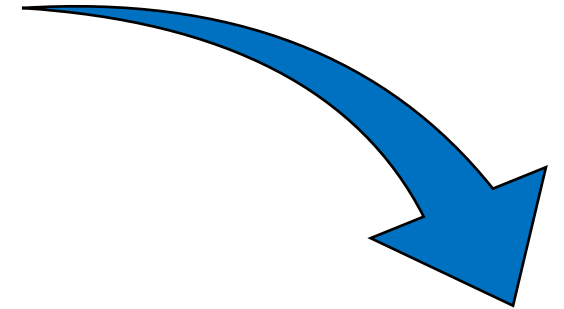
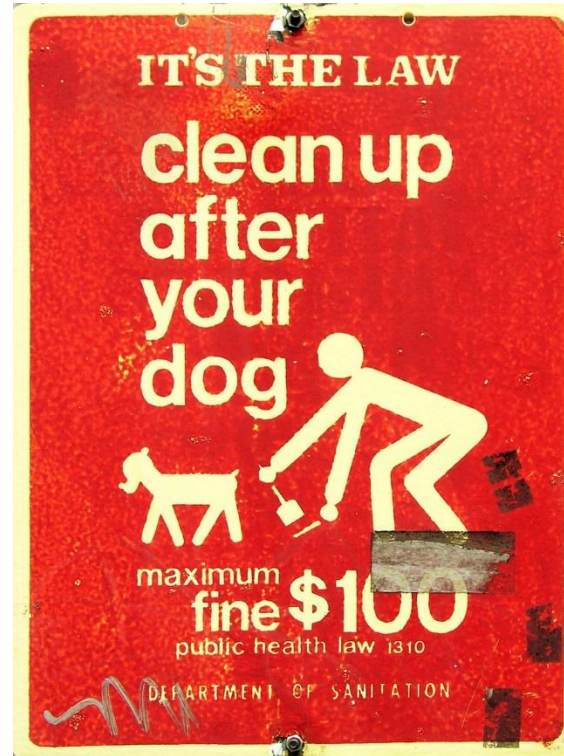
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Special thanks to ACRP and our presenters.

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