

Restarting Studies Post-COVID: For Sites, By Sites



Brian Craig, CEO, Pillar Research, LLC.:

Managing sponsor expectations/enrollment (adjusting timelines, getting up to speed)
Requesting the appropriate support from a contract/budget perspective.



Kate Templeton, MS, Clinical Operations Manager, Segal Trials:

Risk/Mitigation policies (managing flow of visits, PPE, sanitation, etc)
Ensuring employee wellbeing.



Elan Cohen, Ph.D, Principal Investigator, Hassman Research Institute:

Bringing furloughed employees back for adjusted hours congruent to visit activity; overall staffing review.
Utilizing remote/virtual options when available or appropriate.

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POST COVID Sites: Focused on Efficiency and Productivity

- Leaner and more efficient (less admin and support staff)
- Leverage technology (e-source, e-reg)
- Social media/marketing savvy
- Be sensitive to unwieldy study designs:
 - budget conscious, profit focused, cash flow sensitive
- Be sensitive to uncertainty - cautious about investing in new staff
- Consider fewer studies with higher enrollment per study with Sponsors that stay open



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Principles of Study Design under COVID:

- Beware there is pent up demand for studies and sites
- Focus on your primary outcome measure
- Decrease time in the office for visits (but frequent visits are important for retention)
- Compress the study as much as possible - is this the shortest feasible study design?
- Simplify studies when possible - Should X really be a deviation or can we leave it flexible? Increased deviations, decreased efficiency
- Reduce vendors & reduce vendor/site interactions - do I really need this service?
- If COVID testing will be integrated into the trial allow it to be done via prescreening process remotely - Don't inadvertently force you site to close
- If training required, train in advance of study opening
- Consider 2 stage enrollment:
 - 1st stage - sites that remained open and can enroll;
 - 2nd stage - sites that closed can open in 2nd wave once conditions clear



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Budget Principles:

- Allow for increased costs of remote monitoring - scanning/rescanning, increased staff time (video conferencing), drug accountability, etc.
- Increased advertising to sites - social media, TV, radio - traditional face to face methods are more difficult now
- Request an additional per subject recruitment fee
- Build line items for e-reg, e-source, PPE
- Request increased admin fees to allow support for site ongoing monitoring of county, state, and federal COVID regulations
- Request ability to pay some subjects in full up front

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Clinical Operations Manager, Segal Trials:**

Risk/Mitigation policies (managing flow of visits, PPE, sanitation, etc.).

Ensuring employee wellbeing.

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Risk Mitigation:

- Entrance Policies (Volunteers and Clients)
 - Screening Questionnaire
 - Temperature Checks
- PPE
 - For entrance, while onsite and for all work procedures
 - Procurement/Regular Inventory
- Distancing
 - Transportation, Office space, Common Areas
 - Partitions
 - Reduce traffic: Virtual prescreens, staggered appointments

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Risk Mitigation:

- Sanitation Policies
 - Establish a schedule in addition to after each contact
 - Identify Staff
 - Remove unnecessary items
- Hand Washing/Sanitizer
- Signage throughout facility
- Crisis Management Team
 - Compliance and Adherence Checks



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Employee Wellbeing

- Remote vs. Onsite
- Flexibility
- Find ways to stay connected
- Virtual Meetings
- Provide local resources
- Employee Assistance Programs
- Prioritize their Safety
- Clear policies, compliance checks/accountability, communication and feedback
- Make time for fun (activities, outreach, collaboration)

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Elan Cohen, Ph.D, Principal Investigator Hassman Research Institute:



Bringing furloughed employees back for adjusted hours congruent to visit activity; overall staffing review.

Utilizing remote/virtual options when available or appropriate.

Concerns patients and study participants have expressed being in a study related to COVID19.

How is the site managing CRA visits and monitoring.

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Stay Safe and Stay Well.

Wednesday, June 24, 2020

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Thank you!

www.TheSTARR.org



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