CARLE HSPP FAQs FOR COVID-19

1. **Who can I contact in the Stephens Family Clinical Research Institute (SFCRI) with research questions I don't see listed in these FAQs?**

   Grants and Contracts: kathy.dams@carle.com
   Human Subjects Protection Program & IRB: molly.caldwell@carle.com
   Investigator-Initiated Research Services: emily.wee@carle.com
   Research Operations: kathy.dams@carle.com

2. **Will Carle's Human Subject Protection Program (HSPP) and Institutional Review Board (IRB) continue to operate as usual?**

   Yes. The HSPP and IRB committee are operating per standard procedures. For the protection of Carle patients, Stephens Family Clinical Research Institute reserves the right to evaluate the implementation timeline of research procedures during this rapidly changing health landscape.

3. **Are new research projects being developed and initiated?**

   Yes. New study development and initiation continue to occur. However, this may change should the rapidly changing health landscape. Please work with your clinical research manager and/or the Investigator Initiated Research Services (IIRS).

4. **Should I develop a contingency plan?**

   Yes. HSPP is strongly encouraging all investigators to proactively develop a contingency plan and communicate it to your research team. Assess if the disruption of a research protocol might impact the safety of your research participants. The plan should include possibilities for:

   i. Continuing or halting data collection.
   ii. Regularly communicating with the following to ensure everyone is operating under the procedures recommended by Carle: Your research team, study sites, participants, and their caregivers.
   iii. Identifying research priorities in the event Carle employees are not able to come to work.
   iv. Managing data in the event the Carle Hospital or its campuses are closed for research purposes.
   v. Arranging for the possibility of remote access to research files.

   Investigational drugs: If research participants are on investigational drugs, work with the research sponsor and/or study PI to develop a plan if the investigational drug cannot be dispensed to your research participants. If the investigational drugs cannot be dispensed to research participants, you should make plans to transition research participants back onto their most appropriate clinically available medications. This transition should include consultations with the sponsor and/or PI and the clinical team caring for the research participants.

Research procedures: PIs need to assess whether any reduction in staff makes it unsafe to complete the planned research procedures. Even starting IVs might not be easy or safe if experienced staff are not available.

Timely review of research data: If research team members are not available, integration of research care such as reviewing lab results in a timely manner might not be possible and will require special attention under the direction of the study PI. Study teams should consider the availability of appropriate back-ups to the PI to make safety assessments.

5. Do I need to let the Carle IRB know if I plan to halt study enrollment?

No. This does not need to be reported to the Carle IRB unless the study hold is initiated at the request of an external funding agency or the study's Data and Safety Monitoring group *(if there is one)*.

6. Can I screen, recruit, and consent new subjects to IRB-approved research?

Enrollment in research conducted at Carle may continue, however, this may change should the clinical situation become unclear. Please work with your clinical research manager and the study PI to determine whether screening, recruitment, and consent should occur for each study. Consider ways to limit in-person interaction with subjects and adapt research-related activities to comply with social distancing. This may include conducting the informed consent discussion and study visits remotely via phone or video conferencing.

7. Can I still conduct research procedures and interact with subjects?

Researchers should be considering ways to limit in-person interaction with subjects, and considering alternative ways to continue study procedures in the event that in-person visits are not possible.

PIs and researchers should prioritize the health and safety of project personnel, collaborators, and human subjects when deciding how to move forward with research activities.

Research involving vulnerable populations, individuals over age 70, or individuals with underlying health conditions should take special precautions *(CDC guidelines: https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html)*.

PIs and their research teams should prepare how to temporarily postpone, limit, or adapt research-related activities in a manner that protects safety of researchers, participants, facilities, and equipment, should research activities need to be restricted in the near future *(See "Should I develop a contingency plan?")*.

Procedures that are approved as in-person may need to be temporarily changed to occur remotely or postponed. Procedures that do not require in-person contact with subjects can continue as approved in the IRB-approved study protocol.

8. Can I conduct the informed consent discussion remotely? NEW 04/01/2020

Yes. Due to COVID-19 control measures, investigators and their research teams are being asked to limit in-person interaction with subjects and adapt research-related activities to comply with social distancing. This includes conducting the informed consent discussion remotely via phone or video conferencing.

Although the avenue of communication may change, the **content** of the remote consent discussion should not deviate from standard informed consent procedures. The informed consent document and HIPAA authorization, if applicable, should be sent to the potential subject via mail or email *(please note that email must be encrypted)* to obtain the subjects signature. The subject should receive a copy of their signed informed consent and must receive a copy of their signed HIPAA authorization form. This should all be documented in the subject medical record and/or research record, when applicable.

9. Do I need IRB approval in order to contact subjects to determine COVID-19 exposure or symptoms?

No. If you identify subjects whose visits should be postponed, modified, or delayed, you do not need to modify the study protocol because this activity is not a research procedure. Following recommendations set forth by Carle, determine COVID-19 exposure or symptoms through questionnaire or other procedures. If answers indicate exposure or symptoms, subjects should contact their primary care physician (PCP) immediately.

10. Am I required to seek IRB approval if I need to make changes to research procedures due to COVID-19 control measures? NEW 04/01/2020

If a PI chooses to temporarily modify their study procedures to replace in-person study visits with virtual or phone options for administering questionnaires, surveys, check-ins, screening, and consenting **due to COVID-19 control measures**, IRB review and approval is not required, **so long as the changes or deviations from the protocol do not put subjects at increased risk**.

Other examples include delaying or missing/cancelling study visits, lab tests, imaging tests, treatment, and/or biospecimen collection if the delay/omission of a visit outweighs the risks of exposure of the patient to the virus by coming in for an in-person visit and an alternative method is not possible.

These types of changes would be considered **minor protocol deviations** and should be documented in the medical record and/or research record, as appropriate. They should also be recorded in a Carle IRB *Minor Protocol Deviation Summary Log* noting the reason for the deviation *(e.g.,*

restrictions due to COVID-19 control measures) and a brief justification as to why the deviation was considered minor *(e.g., minimal risk questionnaire conducted via skype)*. Minor protocol deviations should be submitted to the IRB at the time of continuing review.

Temporary changes made to study procedures due to COVID-19 control measures that deviate from the protocol will be considered minor so long as the changes or deviations do not put subjects at increased risk. If you need to change an approved study visit in order to eliminate apparent immediate hazards to research participants, this would not be considered a minor protocol deviation and must be reported to Carle IRB via a *Prompt Reporting Form* within 5 days.

11. What if I need to implement a protocol change to eliminate an apparent immediate hazard to subjects? NEW 04/01/2020

Federal regulations (HHS 45 CFR 46.108(a)(3)(iii) and FDA 21 CFR 56.108(a)(4)) and Carle policy IRB801 *Unanticipated Problems and Other Events Requiring Prompt Reporting* permit researchers to immediately implement a protocol change without IRB approval ONLY when the change is intended to eliminate an apparent immediate hazard to subjects. These protocol changes may impact the risk level to the subjects and thus may be considered more than minimal risk.

Eliminating immediate hazards may include reaction to a perceived hazard or an event that exceeds the parameters set in the approved IRB application. **These types of changes are generally expected to be rare.** Investigators should use their best judgement in determining how to proceed without IRB approval in these scenarios. Note that permission/advice of sponsors may be necessary for evaluating modifications for investigational agents.

If a study team determines it is necessary to make a protocol modification to eliminate apparent immediate hazards to subjects, these modifications can be made without prior Carle IRB approval but must be reported within 5 business days via IRBNet. *(NOTE: Additional reports to FDA may be needed if the Carle PI is also IND/IDE holder.)*

Process for IRB submission:

1. Complete a Carle *Prompt Reporting Form*: Select (#5E) 'Protocol changes made without IRB approval to eliminate a hazard to subjects.'
2. Email the form and supporting documentation *(such as sponsor's approval or other similar documentation)* to regulatory@carle.com. Regulatory will formally submit to the Carle IRB via IRBNet.
3. If a permanent change to the research study must occur, a *Modification Request Form* should be completed and submitted to the IRB in a separate submission package *(refer to submission process in #2 above)*.

12. What changes require a Modification or a Report of New Information (via a *Prompt Reporting Form*)? NEW/UPDATED INFORMATION 04/01/2020

a. Halting, delaying, or revising monitoring procedures that prevent an **immediate apparent hazard** to one or more participant and did not have time to obtain prior IRB approval, **or**

b. Halting, suspending, re-scheduling, or delaying procedures for current participants in studies with **ALL** of the following characteristics:
   i. The study involves an intervention *(i.e., not observational or no contact)*, **and**
   ii. The study involves more than minimal risk to the participants *(i.e., it was initially reviewed by the full convened IRB instead of minimal risk "expedited" review)*, **and**
   iii. The suspension potentially has an impact on safety monitoring or the study's scientific integrity

13. I need to monitor subjects for safety. Can I continue to do so?

Researchers should plan for alternatives to in-person monitoring visits, when possible. Some clinical studies require in-person study visits in order to conduct safety monitoring of the subjects.

If you do need to change an approved study visit in order to eliminate apparent immediate hazards to research participants, please report it to Carle IRB via a *Prompt Reporting Form* within 5 days.

14. Can I remove research and/or health data that includes protected health information (PHI) from the covered entity and bring it to my home if I am working remotely?

Please refer to Carle's policy on **the use of adequate safeguards for the protection of protected health information**: IM204 *Adequate Safeguards for Protected Health Information*.

Carle and SFCRI employees should strictly adhere to the following:

1. Only take home the *minimum necessary* and what is considered essential for work.
2. Must have one up/supervisor approval.
3. Look to IM204 for Information Safeguards. It provides safeguards for working from home.
4. Complete a HIPAA Report if there is any inadvertent disclosure to friends or family.

15. Do I still need to submit a *HIPAA Incident Report* if a breach of confidentiality occurs? NEW 04/01/2020

Yes. HIPAA regulations remain the same. If a breach of confidentiality has occurred, please complete a *HIPAA Incident Report* via CLICK. A breach of confidentiality would include lost or stolen laptops storing participant information; lost or stolen USB/thumb drives with unencrypted participant information; sensitive PHI sent to the wrong person; faxes sent to the wrong fax machine outside of Carle; paper with PHI not disposed of properly *(i.e., shredded)*; mailing, emailing, or otherwise communicating *directly identifiable* study participant information to an unauthorized individual *(e.g., name, mailing address, SSN, etc.).*

16. Are there any drugs approved to treat COVID-19? NEW 04/01/2020

No. There are no drugs currently FDA approved to treat patients that have tested positive for COVID-19. Enrollment in clinical trials is the primary way to access investigational drugs that are not

FDA approved. Stephens Family Clinical Research Institute (SFCRI) is pursuing clinical trial options for treatment and prevention via the NIH and industry partners.

If a clinical trial is not available, some FDA-approved drugs may be used **off-label** and investigational drugs may be obtained through an **expanded access** pathway.

Off-label means the medication is being used in a manner not specified in the FDA's approved packaging label *(i.e., the drug was FDA-approved to treat one condition, but is not FDA-approved to treat the condition you are trying to treat)*.

Expanded access allows patients with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product *(i.e., drug, biologic, or medical device)* for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

17. What do I do if I have a single patient emergency use or expanded access request for an investigational drug or device?

The procedures for a single patient emergency use of an investigational drug or device remains unchanged during this time. Please refer to IRB policy 502: *Emergency Use and Other Special Situations in Research*. Contact the IRB office in the event an emergency use scenario arises. (FDA Guidelines: https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use)

FDA guidance regarding patient expanded access programs: https://www.fda.gov/news-events/expanded-access/expanded-access-information-physicians

18. What should I do if my study involves an external IRB and not the Carle IRB?

Each non-Carle IRB may have different policies for what to report about halting/suspending enrollment, activities, etc. If you are changing study procedures or moving from in-person visits to phone visits, you may need to modify the study. Check with the IRB of oversight to determine next steps. For multi-site studies, you may need to work with the coordinating center, lead study team, sponsor or CRO as part of implementing changes.