

Research Guidance in Response to New Visitor Restriction Policy for Banner Facilities – UPDATED 5.1.21

Guiding principles: The goal of this memo is to update the guidance surrounding non-essential research and research personnel operating in a non-clinical care capacity within Banner facilities associated with the University of Arizona (see #3 and Table, below). This update continues to balance safety to both research personnel, study subjects and compliance with local & federal (NIH) regulatory and research safety protocols that may be modified as needed. The different elements of safety that require a fine balance are derived from several avenues: COVID-19 exposure, study-related interventions that may require monitoring, and patient clinical care that oftentimes occurs in areas where research is carried out, among others. The primary focus is to protect research participants, researchers and the larger community from risk of infection with COVID-19 as well as to ensure ongoing access to research that may provide essential support and care to participants. This update focuses on changes to clinical research gating criteria at Banner in response to lower COVID-19 positivity rates and the increasing number of vaccinated research personnel and participants.

Necessary and ongoing mitigation measures: In general, any in-person research encounter or visit for both observational and therapeutic research occurring in a Banner Health facility that can be converted to a virtual or telephonic visit should continue to be conducted remotely. For those research visits that cannot be conducted remotely, the frequency of these visits should be decreased. Consenting of patients should continue to be conducted remotely whenever possible.

- 1. COVID-19 Research:** All COVID-19 studies occurring in Banner Health facilities may continue at this time. COVID-19 research activities may occur in designated COVID-19 areas and select clinics, outpatient, and inpatient environments granted that proper precautions are followed. Permissible research activities include but are not limited to facility-based participant recruitment, participant interviews, biospecimen collection, imaging acquisition, interventional procedures, physical assessments.
- 2. Clinical research involving clinical interventions that have the potential to be lifesaving or disease-altering (i.e. oncology):** These studies may continue to recruit, enroll and monitor study subjects in Banner Health facilities with proper COVID-19 safety precautions. Permissible research activities include but are not limited to facility-based participant recruitment, participant interviews, biospecimen collection, imaging acquisition, interventional procedures, physical assessments.
- 3. Research that involves clinical visits, obtaining clinical samples during planned clinical procedures or that are protocol mandated for lifesaving or disease-altering studies, or obtaining observational or safety monitoring data:** These visits may continue in conjunction with a clinical standard of care visit or procedure that the participant has scheduled or is protocol required. Permissible research activities include but are not limited to biospecimen collection, imaging acquisition, interventional procedures, physical assessments, safety monitoring. These visits should occur in close collaboration with individual Banner Health facility leadership team (specifically in the OR, ICU, ED, outpatient procedure areas/clinics), follow all proper COVID-19 safety precautions and will be subject to facility procedural triage guidelines if/where deemed necessary. Research visits that are not aligned with clinical standard of care visits or those that require additional personnel in Banner facilities may now be resumed with proper COVID-19 safety precautions in place. These activities include biospecimen collection requiring additional research personnel in Banner facilities (OR, ED, ICU, procedure areas) and observational and ancillary research that requires visits to Banner facilities outside of standard clinical visits.

4. **Sponsor Monitoring Visits:** It is encouraged that all external sponsor monitors be fully vaccinated prior to conducting monitoring visits that need to occur in Banner Health facilities. Otherwise, the visit should be held remotely. .

For studies that involve research visits/procedures (with exception of research covered under 1-3 above)

Study status	Plan	Mitigation strategies
Not open, not recruiting	May open and begin new recruitment	<p>In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatory procedures as needed.</p> <p>Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit.</p> <p>UArizona research staff will be allowed on site as needed but will collaborate closely with Banner Health clinics and hospital operations and will abide by all safety standards currently in place.</p>
Open, not recruiting	May begin new recruitment when appropriate. Continue monitoring as required by regulatory procedures.	<p>In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatory procedures as needed.</p> <p>Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit.</p> <p>UArizona research staff will be allowed on site as needed but will collaborate closely with Banner Health clinics and hospital operations and will abide by all safety standards currently in place.</p>

<p>Open and recruiting</p>	<p>May continue new recruitment. Continue monitoring as required by regulatory procedures.</p>	<p>In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatory procedures as needed.</p> <p>Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit.</p> <p>UArizona research staff will be allowed on site as needed but will collaborate closely with Banner Health clinics and hospital operations and will abide by all safety standards currently in place.</p>
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