**Policy: Center for Advanced Reproductive Services:**

**COVID-19 Management and Mitigation**

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| **Prepared by** | **Date Adopted** | **Supersedes Procedure #** |
| MR/PV/AFB |  2/24/21 | 1/19/21 |

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**SARS-COR2 (COVID-19) Outbreak:**

Similar to influenza viruses, SARS-CoV-2, the virus that causes COVID-19, has the potential to cause extensive outbreaks. Under conditions associated with widespread person-to-person spread, multiple areas of the United States and other countries may see impacts at the same time. In the absence of a vaccine, an outbreak may also be an extended event.

CARS will maintain communication and follow guidance from federal, state, and local health agencies to incorporate their recommendations and resources into workplace-specific plans.

**Suspension of Operations**:

In the event that a mass outbreak of COVID-19 poses a substantial threat to public health as well as a strain on the hospital system and supply of PPE, the decision may be made to suspend operations at CARS. The protocol and decision for suspending operations will be formulated and presented by the CEO, physicians and management team. During the time of suspended operations, CARS will limit the amount of staff in the building to as few as necessary for each department. Other employees will telecommunicate from home whenever possible. On-site procedures will be limited to urgent pregnancy ultrasounds, male and female oncofertility cases and other cases determined to be of an urgent nature. The following COVID-19 risk mitigation procedures and policies will be followed during this time of suspended operations:

* PPE – see details under resumption of operation section below. For patients that do need to be seen or treated on-site during a pandemic related shutdown, PPE will be used according to the chart listed below.
* All staff will wear masks at all times unless sitting alone at their desks.
* Social distancing: CARS will enforce a strict practice of social distancing in order to maintain a distance of at least 6 feet between people whenever possible. Large group activities including lunches, conferences, or other congregations of greater than 3 people will not be allowed. See details on social distancing under “resumption of operations” listed below.
* Male patients will be required to bring their semen specimens from home whenever possible.
* All patients, staff and visitors will be screened for possible COVID-19 infection risk every day prior to entering the facility. Temperatures will be taken and a series of screening questions will be asked based on the most up to date recommendations from the local government. Anyone with a temperature >100.0 °F will be denied entry.
* Visitors will be kept to a minimum and only essential visitors such as patient partners, maintenance workers, etc. will be allowed access for periods of time exceeding 10 minutes.

**Resumption of operations**:

Before reproductive care practices can safely resume, several milestones will be considered, including a sustained reduction in cases in the area and the ability of local hospitals to safely treat all patients without resorting to crisis standards of care.

Local conditions and government regulations will ultimately guide what we can and should offer our patients and when care can be reinitiated.

Prior to resuming, we will ensure that they are adequately prepared to provide patient care in a manner that limits risk to patients, staff, and physicians and other healthcare providers. This includes substantial self-education and staying up to date, as new information emerges, on the risk of disease transmission by symptomatic and asymptomatic individuals. Additionally, an ongoing risk assessment of practice activities and the physical plant will be performed by the practice leadership team using publicly available resources or with the assistance of experts. CARS will adapt the COVID-19 risk mitigation policies and procedures (outlined below) which will include an adequate supply of necessary resources and training for all staff.

**COVID-19 Risk Mitigation**:

**PPE** – A face mask must be worn by all CARS employees at all times unless eating or drinking or sitting at their desks. Enhanced, transmission based PPE will be used in addition to universal PPE as described in the table below (ASRM COVID-19 Taskforce Update #7).



In light of rising COVID-19 positivity rates and based on the recommendations from ASRM and guidelines from the CDC, CARS staff involved in direct clinical patient care must wear medical grade masks (either alone or in addition to a cloth mask) as well as protective eye coverage such as googles, face shields or glasses with side shields. Typical vision related glasses without side shields are not sufficient.

**Staff education**: Staff will be formally trained on the proper use of universal and transmission based PPE as it pertains to COVID-19 risk mitigation. CDC signage for the proper PPE usage will be posted in areas where PPE is donned. Staff will also receive mandatory assignments for instructional videos (available through Medtrainer) specific to COVID-19 alternative health care practices, cleaning and disinfecting surfaces, risk assessment and treatment and social stigma. CARS annual safety and Infection Prevention Training is inclusive of hand hygiene and PPE training.

**Screening prior to entry to buildings**: All patients, staff and visitors will be screened for possible COVID-19 infection risk every day prior to entering the facility. Temperatures will be taken and a series of screening questions will be asked based on the most up to date recommendations from the CDC, state and local government. Anyone answering positive to current screening questions or with a temperature >100.0 will be denied entry. Visitors will be kept to a minimum and only essential visitors such as maintenance workers, etc. will be allowed access for periods of time exceeding 10 minutes.

**Reduced start-up volume:** The resumption of clinical operations at CARS will commence gradually at a reduced volume decided upon by the physicians and management team. Typically, this will start at an approximate 50% reduction in typical patient volumes and gradually increase back to the full capacity. This will allow for a pace that allows new policies and procedures to be operationally observed to ensure that they are working as designed. These operations will be monitored, reassessed and modified as community conditions change, knowledge of the disease increases, and additional resources to mitigate, test for, and combat the disease become available.

The gradual increase in patient volumes will occur based upon an assessment of in house, community, state and national epidemiological infection control evidence and continued successful assessment of mitigating measures and processes implemented at CARS. This is inclusive of CARS staff comfort level with workloads and support, continued available PPE supplies, etc. demonstrating an ability to absorb additional volume in a safe manner

**Social distancing for CARS staff:** Although CARS will maximize the amount of people working from home, given the nature of the business, most staff will be required to be on site at least in some capacity. CARS will enforce a strict practice of social distancing in order to maintain a distance of at least 6 feet between people at the workplace whenever possible. In addition, all staff will be required to wear masks unless they are alone at their desks or work stations. Large group activities including lunches, conferences, or other congregations will be restricted. Signs will be posted in each communal room with the maximum capacities allowed for proper social distancing. Physical barriers will be implemented wherever appropriate and possible (i.e. glass windows, etc.)

**Social distancing** **for CARS** **patients**: While many patients will need to come into CARS for specific procedures, telehealth visits and consults will be implemented whenever possible. For patients that need to come into the CARS facilities the following risk mitigation procedures will be implemented:

* A virtual waiting room will be established in order to reduce the number of patients sharing the waiting room space by requiring them to wait in their cars until the clinician is ready to see them.
* Waiting rooms will be arranged and signs will be posted in each waiting room with the maximum capacity to maintain social distancing.
* Mandatory screening will be performed prior to entry into building (for details see section on screening prior to entry into buildings)
* Males will be required to bring their semen specimens from home whenever possible.
* Partners will only be allowed to accompany patients when absolutely or medically necessary. Telephone communication between patient and partner will be encouraged if needed in order to minimize the amount of people in the building.
* Face to face consults (i.e. after procedures such as ultrasounds or HSGs) will be avoided. Instead, patients will consult with the clinical staff on the phone or using teleconferencing. This can take place immediately following their visit in the car or at a later date or time.

**CARS EMPLOYEES**

**When reviewing CT DPH or CDC Guidelines it is important to understand that CARS falls under the category of Critical Infrastructure Workers [or essential healthcare workers] and are subject to guidelines and risk assessments of this group.**

CARS will remain informed and follow current CDC and local CT DPH recommendations for Healthcare Providers (HCP) Criteria.

**CARS employees who are symptomatic for COVID-19:**

Staff members that display symptoms of COVID-19 (e.g. cough, sore throat, shortness of breath, fever) are not permitted to return to work and should have a COVID-19 test. In many cases, employees will not be able to work from home either as they are encouraged to focus on recovery. Decisions regarding working from home will be made collaboratively with the staff member and their manager.

Symptomatic employees that test negative for COVID-19 may return to work once their symptoms resolve.

**CARS employees with positive COVID-19 results**:

If a staff member tests positive for COVID-19 he/she is not permitted to work in the building and must quarantine/self-isolate for a minimum of 10 days from the onset of symptoms or from the date of the positive test. See below for criteria for returning to work after a positive COVID-19 test.

In many cases, employees will not be able to work from home either as they are encouraged to focus on recovery. Decisions regarding working from home will be collaboratively with the staff member and their manager.

Patients who are in close contact (within 48 hours, and in the absence of PPE) of an employee who tests positive for COVID-19 will be informed that an exposure has taken place.

Fellow employees who are in close contact of an employee who tests positive for COVID-19 will also be informed of an exposure or potential exposure. See detailed section on employee exposure below.

Returning to work after testing positive for COVID-19:

Employees can return to work:

* After at least 10 days have passed since the date of their COVID test **and**
* After at least 24 hours have passed since last fever without the use of fever-reducing medications.
* OR With a negative COVID-19 PCR test.

**Note**:  employees who were **asymptomatic** throughout their infection may return to work once they have a negative test and after at least 10 days have passed since the date of their first positive viral diagnostic test.

Note: employees with critical illness or that are immunocompromised may require consultation with infection control experts prior to returning to work.

**UNVACCINATED CARS employees with exposure to COVID-19 positive person(s) according to the following criteria outlined by the CDC and CTDPH for Healthcare Workers:**

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| **Staff Exposure** | **PPE used** | **Risk Level**  | **Restrictions/Management** | **Return to work**  |
| Social interaction – no PPE, prolonged exposure but single event. | None | High | Must quarantine and test on or after the 3rd day from the exposure.  | With negative test performed on or after 3rd day from exposure.  |
| Social interaction –household member that is self-isolating | None | High | Must quarantine and test on or after 3rd day from diagnosis. May return to work with negative COVID test and further episodic testing.  | With negative COVID test and further episodic testing. |
| Social interaction –household member being cared for by employee (not self-isolating) | None | High | Must quarantine for a minimum of 14 days. A plan for further quarantine and testing will be developed on a case by case basis.  | A plan for quarantine and testing will be developed on a case by case basis. |
| Prolonged (>15 min) contact with patient or visitor or colleague with confirmed COVID-19 | Inadequate PPE according to job description and degree of exposure. COVID positive person was wearing a mask.  | Medium  | Monitor symptoms, obtain COVID-19 test on or after the 3rd day from the exposure. No work restrictions if asymptomatic.  | No restrictions if asymptomatic.  |
| Prolonged (>15 min) contact with patient or visitor or colleague with confirmed COVID-19 | Adequate PPE (including facemask and eye protection and COVID positive person was wearing facemask). | Low | No restrictions Monitor symptoms | No restrictions if asymptomatic. |
| Brief interactions < 15 minutes with known COVID-19 positive person | Any or none | Low | No restrictions, monitor symptoms.  | No restrictions if asymptomatic. |
| Secondary exposure – a household member has been informed of a known exposure to a COVID positive person.  | Any or none | Low | No restrictions, monitor symptoms.  | No restrictions if asymptomatic. |

Unvaccinated employees may also undergo routine serial testing for COVID-19 at the discretion of management.

Staff that have tested positive for COVID-19 and recovered within 3 months do not need to quarantine after an exposure as long as they remain asymptomatic.

Vaccinated employees with known exposures are not required to quarantine. However, if they are residing with an individual that has tested positive for COVID-19 they may be required to undergo serial testing (every 2-4 days) during the time that the positive individual is in quarantine. Vaccinated employees with a known one-time exposure may also undergo testing according to the chart above out of an abundance of caution.

Reminders:

* We should be treating all co-workers and patients as they are assumed to be COVID-19 positive and therefore taking steps to protect ourselves at all times. This includes: Wearing a mask at all times, washing/sanitizing hands often and avoiding hand to face contact. This is CARS policy based on CDC recommendations.
* CARS cannot comment on any specific staff member regarding personal health or COVID-19 testing. Staff, like patients, have a right to privacy under the HIPAA act. Having said that, here is the criteria that would apply to any staff member:
	+ If it becomes known that a staff member (or patient) has tested positive for COVID-19, initial trace contacting will be conducted and any staff member who has had contact with that staff member (or patient) within the 48 hours prior to diagnosis/symptoms will be informed of the potential exposure and will be assessed for level of risk and PPE policy compliance.
	+ All work exposures will be managed as appropriate. In general, any staff member who has experienced a potential work exposure, and has been practicing appropriate PPE, will be advised to continue to come to work and wear a surgical mask at all times work and monitor for any symptoms.

**CARS PATIENTS**

* All front line staff [MDs, RNs, front desk, etc.] are empowered to tell any patient with obvious cold/flu/COVID symptoms to not come into the office regardless of where they are in their treatment or cycle, etc. During this pandemic staff safety trumps patient satisfaction.
* Do not fall into trap of trying to “negotiate down” patients symptoms. Err on side of caution.
* Real time clinical decisions must be made in real time by the clinical team. The management team’s role is not to make clinical decisions.
* Patient calls rarely require an immediate response. Take the time to thoroughly assess the situation and get all the facts to make a safe plan.
* A reasonable response for any patient with suspected COVID-19 is, “due to your symptoms we cannot allow you in the office at this time. Please immediately go for a COVID rapid test and if it’s negative we can do your scan/blood later in the day/tomorrow or if positive possibly cancel your cycle”.
* If a patient reveals cold/flu/COVID like symptoms at any front door screening station they should be told to return to their car and have their RN will call them. There are no passes i.e., “I spoke to my nurse and she cleared me’.

**COVID-19 positive or suspected positive (symptomatic for COVID-19) patients:**

All patients are prescreened before entering the building and are required to wear a face covering at all times.

If patients fail to pass the screening and temperature criteria, they will not be permitted access into the building.

Patients may wear their own mask or will be provided with a mask if they do not have one when inside the building.

CARS staff should use universal precautions at all times when working with patients.

If patients become symptomatic and/or test positive for COVID-19 prior to initiating treatment cycles, all office appointments, monitoring and procedures will be suspended. If patients become symptomatic and or test positive during a treatment cycle, the continuation of their care will be managed on a case by case basis.

Patients who have tested positive for COVID-19 prior to initiating treatment, may not schedule any CARS appointments for **a minimum of 14 days from the date of their COVID test and after at least 24 hours have passed since last fever without the use of fever-reducing medications.**

If a patient becomes symptomatic or tests positive for COVID-19, the staff who have been in close contact with that person will be informed and given further instructions based on the degree of exposure (see employee section above). Staff are to report the development of symptoms or changes in health status to their supervisor.

**For patients who have tested positive to COVID:**

It is not uncommon for a positive COVID PCR test result to again result out positive for up to 12 weeks.

* The patient is not permitted entry into the building for 14 days after the initial positive COVID PCR test is diagnosed. Therefore no procedures, bloodwork etc may be scheduled during this 14 day time period.
* For patients preparing to undergo an anesthetic event (such as retrieval or transfer under anesthesia) and have had a positive COVID test:
	+ The anesthetic procedure must be at least 21 days from the date a positive COVID test (**not start of symptoms**) and the patient must be asymptomatic.
	+ The patient does **not need to be retested** as long as they are asymptomatic and are 21 days post their positive COVID test.
	+ For a D&C anesthetic procedure: anesthetic procedure must be at least 21 days from the date of the positive COVID test (not start of symptoms). No repeat COVID testing after a positive result is needed for up to 12 weeks from the date of the positive COVID test (not start of symptoms) provided the patient has no current symptom
* For IVF cycling patients: cycling stimulation time must be factored in:
	+ IVF patients may cycle as long as retrieval (or transfer under anesthesia ) is 21 days from a positive COVID test (not start of symptoms) and provided the patient has no current symptoms. The patient does not need to be retested as long as they are asymptomatic and are 21 days post their positive COVID test.
* For Cancelled/next immediate IVF cycle:
	+ No repeat COVID test is necessary for retrieval (or transfer under anesthesia) for up to 8 weeks from positive COVID test and provided the patient has no current symptoms. This factors in stimulation time prior to retrieval/anesthetic event.

**Unvaccinated CARS patients with known exposure to COVID-19 positive individual**

Patients with known exposure to COVID-19 positive individuals will be triaged on a case by case basis.

Treatment may be suspended depending on the **level of exposure and PPE used** and in accordance with the following guidelines from the CDC and CTDPH:

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| **Exposure (Patient)** | **PPE used** | **Risk Level**  | **Restrictions/Management** |
| Social interaction – no PPE, prolonged exposure but single event. | None | High | No treatment for 14 days. Can resume treatment after 14 days with negative test.  |
| Social interaction –household member that is self-isolating | None | High | No treatment for 14 days. Can resume treatment after 14 days with negative test. |
| Social interaction –household member being cared for by patient (not self-isolating) | None | High | No treatment during the household member’s quarantine plus an additional 14 days after the end of their quarantine. Will need a negative COVID test to resume treatment.  |
| Exposure with PPE (i.e. Healthcare workers that are patients)  | Inadequate PPE according to job description and degree of exposure. COVID positive person was wearing a mask.  | Medium | No treatment until they obtain a negative COVID test (performed on or after the 3rd day from exposure).  |
| Exposure with PPE (i.e. Healthcare workers that are patients) | Appropriate PPE according to job description and degree of exposure. COVID positive person was wearing a mask. | Low | No restrictions if asymptomatic. |
| Brief interactions < 15 minutes with known COVID-19 positive person | Any or none | Low | No restrictions, monitor symptoms.  |
| Secondary exposure – a household member has been informed of a known exposure to a COVID positive person.  | Any or none | Low | No restrictions, monitor symptoms.  |

**Vaccinated patients**

Vaccinated patients with a known one-time, isolated exposure will not need to quarantine or be restricted from access to CARS facilities or treatments as long as they remain asymptomatic. They will be required to have a negative COVID-19 test on or after the 3rd day of exposure.

Vaccinated patients residing with individuals who have tested positive for COVID-19 may be required to refrain from in-person visits to CARS during the length of their household member’s quarantine. At the end of the quarantine period, they will need a negative COVID-19 test prior to entering a CARS facility.

The guidelines and risk definitions outlined by the CDC (listed above) will be used as a reference but ultimately the CARS physicians and clinical team will decide on the best course of treatment that ensures patient and staff safety.

**Prophylactic COVID-19 testing**:

Whenever possible, CARS physicians will order COVID-19 testing for patients undergoing anesthesia as part of their treatment. These patients present the highest risk of disease transmission during the management of their airways.

For patients undergoing oocyte retrievals, the testing will be ordered at least once between baseline and trigger.

As testing becomes available, additional patient populations may be tested as well.

 **Laboratory considerations related to COVID-19 risk mitigation (also refer to specific IVF lab disaster plan)**:

* When possible and during time of high positivity rates as determined by the state of CT, the laboratory staff will be assigned to non-overlapping teams to reduce cross-contamination of staff should an exposure occur. Remote options for all non-bench activities will be available.
* Laboratory staff will be restricted from entering clinic areas that are not required for job function.
* Scheduled cleanings of laboratory surfaces will be maintained and documented. Only disinfectants suitable for a reproductive laboratory will be used within the laboratories.
* Laboratory supplies will be unpacked before entering laboratory and external packaging will remain outside of the laboratory at all times.
* Off-site semen collection will be recommended when possible. Additional time for ample cleaning of collection room will scheduled if on-site collections are required.
* Limiting patient interaction – embryologists will perform “time out” within 6 feet of patient and other staff.
* Correspondence between lab and PACU (and all other locations) will be limited to the telephone or email whenever possible.

**Clinical considerations related to COVID-19 risk mitigation:**

* Clinical staff will follow above stated infection prevention precautions and mitigating patient care activities and precautions.
* See ASC addendum for additional clinical specific activities.

Operational updates:

The following COVID mitigation practices will continue until further notice:

* Virtual waiting room program [patients wait in cars and are texted in
* Virtual New Patient visits.
* SA produced at home [unless > hour away]
* Front door screening and temps
* Scheduled appointments only. No walk in scans or bloods
* Virtual follow up visits
* No children
* Continue weekly testing for unvaccinated staff.

However, the following restrictions will be LIFTED:

* Prohibition on partners. Allow partners [or another family member] in for all live visits. However, PACU is still off limits to partners per anesthesia. No children under any circumstances.
* Start allowing satellite patients in ***IF*** patient was a past patient of CARS.

All of the guidelines outlined in this document are subject to change based upon new local, state and federal recommendations.

COVID-19 vaccination program

* CARS employees are strongly encouraged to obtain the COVID-19 mRNA vaccine. At this time, it is not a requirement. However, those employees who have not received the vaccine may be asked to undergo serial COVID-19 testing at the cost of CARS.

**Addendum to CARS** **COVID-19 Management and Mitigation:**

**Travel to States listed on CT Travel Advisory List**

Mandatory travel restrictions have been lifted in the state of CT, as of March 19, 2021. However, travel advisories remain in effect from both the state and the CDC. With that in mind, while CARS has modified its travel policy for both staff and patients, restrictions will remain in place in order to maintain the safety of the practice.

For all employees and patients:

Any domestic or international travel will require COVID-19 testing within 3 days of return and prior to entry into CARS.

This policy does not apply to travel to any state that borders CT including MA, NY and RI. No testing is required after travel to these states.

This policy applies to all employees and patients regardless of vaccination status.