



INDUSTRY REPORT 2022

SART:

What Role Does it Play in Egg Donor Data Collection?

SART is a Not-for Profit subsidiary of the Not-for profit ASRM (American Society of Reproductive Medicine)



EXECUTIVE SUMMARY

Since 2004, Diana Thomas, founder and owner of The World Egg and Sperm Bank, has been a leader in egg banking. **The World Egg and Sperm Bank continues to suggest ways to eliminate unnecessary liabilities for clinics**, streamlining processes to hold down costs, and, most importantly, advancing egg banking along a path that benefits not just aspiring parents, but the all-important physicians, nurses, IVF clinics, and human gamete donors.

Even though The World Egg and Sperm Bank complies fully with all CDC (Centers for Disease Control and Prevention) regulations for independent egg banks, the Society For Assisted Reproductive Technology (SART) has begun specifically pressuring IVF clinics not to use The World Egg and Sperm Bank's eggs. This anti-competitive behavior must stop. SART has ignored TWESB's written requests to clarify their actions.

The World Egg and Sperm Bank Strictly Adheres to CDC Regulations

Since approximately 2015, SART has stated that the clinic that handles the human embryo is responsible for reporting the egg donor cycle. In the case of independent egg banks, like The World Egg and Sperm Bank, this doesn't make any sense, and in fact, would be fraudulent. It also opens the door to potentially unreliable data because the reporting entity—the clinic—obtains the eggs from an outside egg bank, which is a totally unrelated medical facility, and can't independently verify the reported data.

The CDC specifically recognized that medical directors of IVF clinics are not able to directly verify data provided by an independent external egg bank, and so should not be held responsible or liable for this verification in the CDC Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs, as specifically stated in a notice by the CDC on 8/26/2015:

- Reporting is limited to activities within a clinic, whether it is **1)** one practice, one site, or **2)** one practice with multiple sites, or **3)** multiple ART programs involved in one cycle.
- Individual ART programs report separately under a unique NASS ID.
- Reporting responsibilities lie with the Medical Director of each individual ART program for the activities in that program.
- Reporting is based upon ART CYCLES performed within a program. This reporting also cannot be pooled and reported together by individual physicians who practice independently.

The World Egg and Sperm Bank physicians are independent of cycles performed by other physician groups.

SART's inappropriate conflation of independent egg banks and IVF clinics likely stems from the accelerating number of mergers and acquisitions and consolidations in the IVF world. Many egg banks—through affiliations, network agreements, or shared ownership—may be considered part of the “clinic that handles the embryo.” Thus, the references to donor oocyte banking by SART are addressed to these clinic-affiliated egg banks, including those eggs imported from IVF clinics from foreign countries, which is a whole separate and significant problem for the USA to begin to regulate.

According to the CDC, The World Egg and Sperm Bank is not an IVF ART program. We do not share resources or liabilities with any other stand-alone IVF clinic, and we do not treat patients who have infertility etiologies, nor do we provide ART services to patients for other reasons. Therefore, the only donor information from The World Egg and Sperm Bank that the CDC requires IVF clinics to report is: race, ethnicity, and date of birth. As an independent egg bank, The World Egg and Sperm Bank, of course, provides this information to clinics for all our donor eggs to fully comply with CDC requirements.

Where Does That Leave Clinics Who Report to SART?

SART perpetuates the fallacy and confusion of **non-mandatory** data collection/reporting with **mandatory** data collection/reporting. In essence, SART has then placed itself between aspiring parents, clinics, and egg banks by producing a ranking system that limits the options of clinics and their patients when it comes to egg bank choice.

The solution is to rein in this overreach and unravel SART's hold on clinics and their self-determined ability to impose punitive measures (remove your ultimately hollow designation as a center of excellence) if one doesn't provide the non-mandatory CDC data requirements. There are many excellent IVF clinics in the U.S., but SART is not the 'authority' to decide who these are.

The glaring ethics problem is that SART has improperly imbued itself with regulatory status and in fact, has no contract with the CDC to collect data. Westat representatives state that the contract to provide the CDC with data has been with Westat, an independent database company, since 2004. According to Westat's representatives, SART offers 'help' to make sure data is entered "because they have 80% of clinics as members." Ironically, the primary reason SART has all of these paying members, is because SART carries the big stick and tells clinics they won't be SART and ASRM compliant if they don't report to SART, even though SART has no regulatory status.



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SART expects IVF clinics to complete both mandatory and non-mandatory fields for the clinics to 'earn' a high ranking from SART (3-tier ranking system). *SART then provides that ranking information to patients' medical insurance carriers for the carriers to approve clinics. By doing this, SART can, in effect, regulate which clinics get preferential treatment from carriers.* Further, SART can determine that a clinic doesn't rank at all, thereby redirecting business (patients who can get insurance coverage) to other IVF clinics.

It is untoward and anticompetitive for SART to force clinical practice participation or face "removal for non-compliance" from insurance rosters.

The SART mission statement says: "SART is the primary organization of professionals dedicated to the practice of IVF or assisted reproductive technology (ART)." How then, can SART also claim to establish industry practice standards when it is trying to force IVF clinics to report on egg retrieval cycles from outside independent medical facilities that cannot possibly be known to the reporter? Doesn't ASRM claim to issue IVF clinic regulatory guidance? In fact, all of SART's "guidelines" are the same guidelines produced by ASRM, because SART is one of three tax-related entities to ASRM and shares an address, and a telephone number.

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SART also appears to share with ASRM a tendency to file delinquent tax returns with the IRS. They remain several years late in filing tax returns. So, while incorrectly and maliciously professing that The World Egg and Sperm Bank is noncompliant in reporting data, SART—reporting over **6 million dollars** in assets on its **2018** tax returns as a non-profit (990), with half of that 'invested in securities'—ignores its own compliance. For **2020**, ASRM reported over **75 million dollars** in assets on its tax returns, with half of that 'invested in securities.'

But SART's Vice President Elect has already been telling clinics, in public online teaching forums and one-on-one with clinics, not to use gametes from The World Egg and Sperm Bank if it won't provide non-mandatory SART fields to the clinics. Such business interference with clinics should be stopped, as should their ability to manage who receives referrals from insurance companies for patients.

Already, some clinics have written SART requesting that non-mandatory fields be removed so that they can continue to use The World Egg and Sperm Bank gametes without being punished. IVF clinics are powerless to change the landscape if they are willing to give their power away without inquiry.

There is a simple solution: SART must remove the non-mandatory fields (convert these fields to 'soft' fields), and clinics can continue to report to SART with 100% compliance. Or clinics can directly report to the CDC and can remain 100% compliant with the CDC (and hence, they should also comply 100% with SART). The question then becomes, if SART is not contracted to collect data,



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SART is not a regulatory authority that can 'rank' clinics for insurance purposes, and SART piggybacks off of ASRM's guidance documents, what is gained by paying SART for every cycle a clinic enters? Any other 'perks' SART provides, should equally be available to every member of ASRM.

At the very least, SART should be held to an accurate representation of their role, accountable for collection of funds from clinics that should not and cannot be tied to any reward or punitive regulatory role, and for interfering with business and negatively re-directing clinics and patients at will. This should not be acceptable to anyone in IVF.

We ensure that we fully comply with the laws and regulations of all the countries, provinces, states, and jurisdictions we serve.

The World Egg and Sperm Bank Results

1.18 embryos transferred to each patient

2.78 embryos (transferable/ freezable) for each cohort of 6 eggs

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