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INTRODUCTORY INFORMATION

This guide provides step by step instructions for submitting annual data required by the Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 through the National Assisted Reproductive Technology (ART) Surveillance System (NASS) at www.artreporting.org. Federal Register notices are posted on the NASS website that describe who is required to report to CDC and the process for reporting. Section 2.8 of the NASS User's Manual describes how to access the Federal Register Notices.

Reporting Deadline - The deadline for reporting 2007 data is December 15, 2008. An ART program will not be considered to be in compliance with the federal reporting requirements of FCSRCA if the ART program was in operation in the full year that is being reported, i.e., the clinic was in operation after January 1 of the reporting year, and fails to submit a dataset to Westat in the required data reporting system (NASS) by the reporting deadline. ART programs considered to not be compliant with the federal reporting requirements of FCSRCA will be listed as non-reporters in the 2007 Assisted Reproductive Technology Success Rates report.

Required Documents - As part of the annual reporting process, your clinic will need to submit the hardcopy documents listed in the table on the following page to:

NASS Processing Center
Westat
1450 Research Boulevard, Room TC1021F
Rockville, MD 20850-3195
Phone (if required by overnight couriers): 1-888-650-0822

Beginning the Annual Submission Process: The annual reporting year submission process in NASS includes five steps that are explained in the remainder of this guide. The NASS Submit Annual Data screen walks you through this process step by step, and includes links to the documents and reports that you are required to review and/or submit to Westat. (The table on the next page summarizes the complete list of documents that must be sent to Westat.)

Required Documents for Annual Submission	Clinic Signature Required?	Submit Copy or Original	Additional Information/Directions Available
Comprehensive Edit Report	Yes Data Manager or Medical Director	Original	Section 3, NASS Annual Submission Guide
Annual Submission Clinic Table	Yes Medical Director	Original	Section 4, NASS Annual Submission Guide
Certificate proof of embryo laboratory accreditation	No	Copy	Section 4.2, NASS User's Manual
Letter documenting clinic reorganization (if applicable)		Original	Please contact the NASS Help Desk for further information 1-888-650-0822

To access the Submit Annual Data screen and begin the submission process, you must log into NASS and select the reporting year for which you are submitting clinic and patient cycle data (see Section 3.2 of the NASS User's Manual). This will take you to the Select/Add Patient Screen shown below.

- What's New in NASS
- Select Reporting Year
- Select/Add Patient**
- Update/Add Cycle
- Update Patient Profile
- Clinic Profile & Data
- Exporting/Importing
- Reports
- Documents
- User's Manuals
- System Utilities
- Help
- Logoff

Select/Add Patient

Find Existing Patient

To find an existing patient, search by entering any combination of Date of Birth, Optional ID 1 or Optional ID 2. For a list of ALL patients, leave search fields blank and click Find button.

Date of Birth: / /
mm dd yyyy

Optional Identifier 1:

Optional Identifier 2:

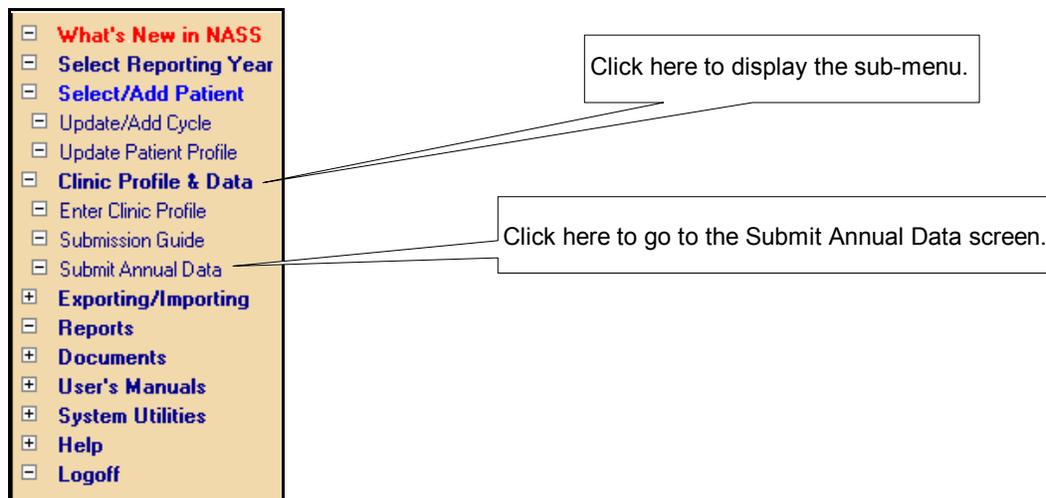
NASS Patient ID:

Add New Patient

To begin the process of adding a patient, enter the patient's date of birth.

Date of Birth (mm/dd/yyyy):

Once you are in the Select/Add Patient screen, go to the menu on the left hand side of NASS and click on the *Clinic Profile & Data* menu item to view the sub-menus (see below).



Select *Submit Annual Data* from the sub-menu by clicking on it. This will take you to the Submit Annual Data screen shown in Appendix 1 at the end of this guide. Follow the instructions and steps on the Submit Annual Data screen. Please keep in mind the following procedures when completing this step by step process:

- The reports shown as links in the Run Report column of the screen can be selected and run in any order for you to review. However, the reports may not be complete or final depending on the status of patient cycle and clinic data entry at your clinic.
- You must indicate that each step is complete by checking the corresponding Step Completed box before moving on to indicate that the next step is complete. For example, after completing Step 1, you must enter and save a check mark in the corresponding Step Completed box prior to being able to save a check mark for completing Step 2. If you do not complete the steps in the order shown, you will see the following message when trying to save work in progress.

**Inconsistent data have been entered as described below. Please resolve and save data.
The report submission steps must be completed in the sequence listed on-screen.**

- If you wish to save your check marks, and have not completed all steps of the submission process, you can click the Save Completed Steps button at the bottom

Click the Save Completed Steps button if you want to save this page BEFORE completing all 5 steps – that is, if you have checked the Step Completed box for some, but not all steps. Please note: Clicking on this button will **not** submit your data for the CDC annual report.

Save Completed Steps

of the Submit Annual Data screen (see next page). This way, the next time that you pull up this screen, check marks you have entered for completed steps will show.

- A check mark must be entered and saved in all four Step Completed boxes (for Steps 1 through 4) before being able to submit your data to Westat by pressing the Submit Final Annual Data button at the bottom of the screen. If you have not

Step 3	Section 3	This report must be rerun until all inconsistent data have been corrected in NASS and unlikely data have been reconciled or confirmed. Handwritten notes on the last run of the Comprehensive	Comprehensive Edit Report	<input type="checkbox"/>
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Microsoft Internet Explorer

 Step 3 has NOT been marked as completed. Data cannot be submitted until all checkboxes have been checked.

OK

After completing Steps 1-3, run the Annual Submission Clinic Table

checked through all the steps, you will see a message similar to the one below indicating which steps you have not completed and saved.

In addition to on-screen instructions, additional information about each step is provided below in Sections 1 through 5 of this guide. If you have further questions, please contact the NASS Help Desk for assistance at 1-888-650-0822.

A Note to Importers - The annual submission process includes the same steps described in this guide for all clinics whether they have chosen to use a vendor or other medical record system to import their data into NASS. ***Please note that clinics who have chosen to submit their data to SART must also comply with these instructions.*** Clinics using alternative medical record systems to enter and manage their data for import into NASS are responsible for ensuring that their data can be accurately extracted and imported into NASS by the reporting deadline.

The annual submission process assumes that import files have passed quality and content checks, and have been accepted and loaded into NASS. Numerous edits and logics have been programmed into NASS to help reduce error in data entry and consistency. Once imported data have been loaded into NASS for all cycles at a clinic, replacement import files will not be accepted to correct erroneous data, or to add additional data. After importing, the following types of cleanup actions **must be performed in NASS**:

- Changing data (e.g., correcting a data point, adding missing data or cycles);
- Marking any incomplete cycles as “Completed”; and
- Updating data (e.g., current clinic address).

Please refer to the NASS Import User’s Guide for additional instructions about submitting your cycle data to NASS through the import process, and for information on data quality checks on imported data. This manual can be downloaded from within the NASS web site.

Section 1. Step 1 - Review Current Clinic Information

The first step in the annual submission process is to ensure that the current clinic information entered in NASS is accurate. The following information will be shown at the bottom of the Clinic Table and included in the CDC annual report appendix exactly as the text has been entered in NASS:

- Clinic name, address, and telephone and fax numbers;
- Name and degrees of Medical Director verifying the data;
- Laboratory name and accreditation details;
- Reorganization status if applicable; and
- Services offered and clinic profile (e.g., donor embryo program, SART member).

The Annual Current Clinic Profile report that can be generated in Step 1 is designed to provide this information on a printout for your review. The information shown on the printout is dependent on how your clinic has answered the Current Clinic Status question in NASS (See Section 4.2.2 of the NASS User’s Manual for details). The Annual Current Clinic Profile report will produce a printout with different clinic information depending on whether you have indicated in NASS that your clinic has reorganized, changed its name, or maintained the same reporting year status.

Click on the report link in the Step 1 row to print this report and review the current clinic information that will be published in the CDC annual report.

Click here to run the Annual Current Clinic Profile Report.

Step	Annual Submission Guide Section	Step Description	Run Rep	Step Completed
Step 1	Section 1	Print the Annual Current Clinic Profile report to check that clinic profile & services data, current clinic name and address, lab information, Medical Director name and degrees, and organization status are complete and accurate as they should appear in the annual report.	Annual Current Clinic Profile	<input type="checkbox"/>

Any changes that need to be made to your clinic information must be done in NASS. To do so, click on the *Clinic Profile & Data* menu item shown on the left-hand side of the NASS screen (note: this menu item appears once you have selected a reporting year in NASS). Select *Enter Clinic Profile* from the sub-menu by clicking on it. This will take you to the first of four clinic profile reporting screens. See Section 4.2 of the NASS User's Manual for further information about entering or updating your clinic profile information.

You may rerun the Annual Current Clinic Profile report until the data are accurate and final. When the clinic information is finalized in NASS as you want it to appear in the CDC annual report, click the Step Completed box for Step 1. You will see an on-screen edit message like the one shown below if you have not entered the minimally required clinic data in NASS. The system will not allow you to check off that Step 1 is complete until data have been entered in all the NASS fields listed in Appendix 2.

A message like this will pop up if required clinic data have not been entered in NASS.

Inconsistent data have been entered as described below. Please resolve and save data.

You have indicated the clinic profile for the selected reporting year is complete. However, some of the required data elements have not been provided.

Step	Annual Submission Guide Section	Step Description	Run Report	Step Completed
Step 1	Section 1	Print the Annual Current Clinic Profile report to check that clinic profile & services data, current clinic name and address, lab information, Medical Director name and degrees, and organization status are complete and accurate as they should appear in the annual report.	Annual Current Clinic Profile	<input type="checkbox"/>

Click here to check off when this step has been completed.

Section 4.2 of the NASS User's Manual provides further definitions and explanations for each of the clinic fields listed in Appendix 2. Please note that the Medical Director name and degrees listed on the report will be the same as printed in the CDC annual clinic table as having verified the data at the clinic. An example of an Annual Current Clinic Profile report for a clinic that has not reorganized or changed its name since the reporting year is included as Appendix 3.

Section 2. Step 2 - Resolve Open Cycles

Step 2 is designed to ensure that all cycles entered for the reporting year have been marked “Completed” in NASS before moving on to Step 3 in the submission process. To check if you have any open cycles in the reporting year, click on the report link in the Step 2 row to print the Annual Open Cycle Report.

Step	Annual Submission Guide Section	Step Description	Run Report	Step Completed
Step 1	Section 1	Print the Annual Current Clinic Profile report to check that clinic profile & services data, current clinic name and address, lab information, Medical Director name and degrees, and organization status are complete and accurate as they should appear in the annual report.	Annual Current Clinic Profile	<input checked="" type="checkbox"/>
Step 2	Section 2	Check for open cycles in this reporting year by running the Annual Open Cycle Report. All cycles must be marked "Complete" in NASS to be included in NASS reports and in the CDC annual report. Open cycles must be resolved in NASS prior to moving on to Step 3. This report should be rerun until it indicates that there are no more open cycles for this reporting year.	Annual Open Cycles Report	<input type="checkbox"/>

Click here to run the Annual Open Cycles Report.

Cycles that have not been marked as complete will be listed in the printout along with other information to help you identify which cycles need to be resolved in NASS before proceeding. See Section 6.8.4 of the NASS User’s Manual for information on how to indicate that open cycles are complete. An example of the Annual Open Cycles Report is shown in Appendix 4.

The Annual Open Cycles Report should be rerun until it indicates that there are no more open cycles for this reporting year. You can then click on the Step Completed box for this step. If you try to put a check mark in this box without having indicated that all cycles for this reporting year are complete (that is – your clinic still has open cycles for this reporting year), you will get the edit message show on the next page.

Inconsistent data have been entered as described below. Please resolve and save data.
You have indicated that all cycles from the current reporting year have been marked as complete. However, there are still cycles that are not marked as complete.

Step	Annual Submission Guide Section	Step Description	Run Report	Step Completed
Step 1	Section 1	Print the Annual Current Clinic Profile report to check that clinic profile & services data, current clinic name and address, lab information, Medical Director name and degrees, and organization status are complete and accurate as they should appear in the annual report.	Annual Current Clinic Profile	<input checked="" type="checkbox"/>
Step 2	Section 2	Check for open cycles in this reporting year by running the Annual Open Cycle Report. All cycles must be marked "Complete" in NASS to be included in NASS reports and in the CDC annual report. Open cycles must be resolved in NASS prior to moving on to Step 3. This report should be rerun until it indicates that there are no more open cycles for this reporting year.	Annual Open Cycles Report	<input type="checkbox"/>

Section 3: Step 3 - Review Inconsistent and Unlikely Cycle Data

Once you have completed Step 2, you must ensure that the cycles entered in NASS do not have any inconsistent data, i.e., data that do not make sense based on the information entered for that cycle. You should also review all unlikely data entered in NASS, i.e., data that are unlikely to occur, but occasionally could be seen, to ensure they are valid. See Section 1.15 of the NASS User's Manual for more information about inconsistent and unlikely data. While a number of logics are built into NASS so that the user can catch inconsistent data as they are being entered, this comprehensive QC checking program needs to be run by the clinic before data can be submitted for the annual report.

To review inconsistent and unlikely data for the reporting year that you are submitting, click on the report link in the Step 3 row to print the Comprehensive Edit Report. **Please note that only cycles that have been marked "Completed" will be shown on this report.** While you can run this report at any time during the year to check on your data, it is essential to make sure that no cycles are open for the reporting year when you are running and reviewing this report as part of the annual submission process. If you were able to check the Step Completed box for Step 2 (the step to review open cycles), then you should not have any open cycle left for this reporting year, and the Comprehensive Edit Report should represent all your entered cycles.

Step 3	Section 3	<p>After completing Step 2, run the Comprehensive Edit Report to review a list of all inconsistent and unlikely cycle data. Please note that the only cycles shown on this report are ones marked "Complete" in NASS (see Step 2). Inconsistent data must be corrected in NASS prior to printing the Annual Submission Clinic Table. Unlikely cycle data should be reviewed to ensure that they are accurate, and corrected in NASS if not.</p> <p>This report must be rerun until all inconsistent data have been corrected in NASS and unlikely data have been reconciled or confirmed. Handwritten notes on the last run of the Comprehensive Edit Report may be made to indicate that remaining unlikely data have been confirmed by the clinic. Please note that handwritten <u>corrections</u> to data on this report will not be accepted. All data changes must be made in NASS.</p> <p>The clinic Data Manager (or Medical Director) must sign off on the final hardcopy of the report and forward this document to Westat with other annual submission materials.</p>	<p>Comprehensive Edit report</p>	<input type="checkbox"/>
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Click here to run the Comprehensive Edit Report

A sample page from a Comprehensive Edit Report is shown in Appendix 5. The report must be rerun until all inconsistent data have been corrected in NASS, and unlikely data have been reconciled or confirmed as accurate. Handwritten ***corrections*** to data on the hardcopy of this report will ***not*** be accepted for the annual submission. However, you may write notes or comments about unlikely data that have been confirmed by your clinic on the final hardcopy such as for values that are higher than usually reported or are outside of an expected range.

When the final report has been run with no more inconsistent data, and with assurance that unlikely data are accurate, you can then click on the Step Completed box for Step 3.

Please note that it is not functionally practical for NASS to perform a realtime scan to determine whether there are remaining inconsistent data issues before allowing you to mark the Step Completed box. Therefore, your clinic is ultimately responsible for ensuring that all inconsistent data have been resolved before you check the Step Completed box for this step.

The clinic Data Manager, or the Medical Director, must sign off on the final hardcopy of the Comprehensive Edit Report, and forward this document to Westat with the other annual submission materials listed in the introduction of this guide.

Section 4: Step 4 - Generate Annual Submission Clinic Table

After Steps 1 through 3 have been completed, you are ready to run and review the Annual Submission Clinic Table. This is the table that will appear in the CDC annual success rate report for your clinic. Click on the report link in the Step 4 row to print the table.

Step 4	Section 4	<p>After completing Steps 1-3, run the Annual Submission Clinic Table to review. If any data are inaccurate, corrections must be made in NASS. Handwritten corrections to data on this report will not be accepted. This table can be rerun until data are ready for submission.</p> <p>The Medical Director must sign off on the final hardcopy clinic table and forward this document to Westat with other annual submission materials.</p>	Annual Submission Clinic Table	<input type="checkbox"/>
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Click here to run the Annual Submission Clinic Table

The generated table will have all the required fields presented in a format similar to that on the CDC annual report. See Appendix 6 for a sample template of what the clinic table will look like generated in NASS. The clinic report pages that are ultimately published by CDC will be formally formatted (e.g., colors, shading, text fonts) for presentation to the public.

The information on current clinic profile and services, reporting year name and city/state, and the Medical Director verifying the data should be the same as you reviewed on the Annual Current Clinic Profile report from Step 1. All cycles that have been marked completed in NASS that are eligible to be included in the report should be represented in the data on this table. If you think that the cycle count is not accurate – either too low or too high – begin by ensuring that:

- There are no open cycles for this reporting year that should have been marked Completed in NASS. See instructions for Step 2 to resolve open cycles.
- Patient cycles have been entered in the correct reporting year in NASS (e.g., a cycle with a start date during 2007 erroneously entered in the 2008 reporting year section of NASS). See Chapter 3 of the NASS User's Manual for assistance with selecting the correct reporting year.
- Your clinic has entered all cycles for all patients. See Chapter 5 of the NASS

User's Manual if you need step-by-step instructions on adding a patient or cycle that should have been entered for this reporting year, or to find an existing patient's cycle(s) that should be in NASS.

- Cycles that should be included in the annual submission report have not been marked "Deleted". See Section 5.7 of the NASS User's Manual for information on how a cycle may have been deleted. Note that your clinic cannot un-delete or retrieve a cycle once it has been deleted from your NASS database. Any erroneously deleted cycles would have to be re-entered before proceeding with the annual submission process.

In addition to the reports available in Steps 1 and 2 of the Submit Annual Data screen, there are the following NASS reports that can be generated and reviewed to check data reported in the annual submission:

- Report-001 lists all cycles that are complete or open for a particular reporting year. Completed cycles are included in the annual table; open cycles are not.
- Report-002 generates the cycle data entered for a specific patient.
- Report-004 allows clinics to review specific data points for all cycles included in the annual clinic success rate table.

See Chapter 8 of the NASS User's Manual for information on generating reports in NASS.

Certain types of cycles will be automatically excluded from the annual submission (e.g., evaluation of new treatment procedures). Contact the NASS Help Desk (1-888-650-0822 or NASS@Westat.com) if you want to find out why one or more of your cycles may have been excluded from the clinic table.

The clinic table statistics may be rerun as often as necessary until the data are ready for submission. Handwritten **corrections** to data on the hardcopy of this report will **not** be accepted for the annual submission. All corrections must be made within NASS prior to re-running and signing the final report. When you have generated your clinic's final Annual Submission Clinic Table, you can then click on the Step Completed box for this step.

The Medical Director must sign off on the final hardcopy of the Annual Submission Clinic Table and forward this document to Westat with other annual submission materials listed in the introduction of this guide.

Section 5: Step 5 - Submit Final Annual Data

You are ready to submit your final reporting year data for publication after Steps 1 through 4 have been performed, the Completed Steps boxes have been checked and saved, and the Annual Submission Clinic Table is final. **Please note that once you have submitted your final data, you will no longer be able to make any changes, additions or deletions to these data in NASS.** However, your clinic may continue to view these data in NASS for this reporting year (i.e., in “read-only” mode).

To submit your data, click on the Submit Final Annual Data button at the bottom of the Submit Annual Data Screen.

Step 5	Section 5	After Steps 1-4 have been performed, and the Annual Submission Clinic Table is final, click on the Submit Final Annual Data button below to submit your final data for publication. Please note that once you have submitted your final data, you will no longer be able to make any changes, additions or deletions to these data in NASS. However, you may continue to view data in NASS for this reporting year. If you discover an error after data submission, please contact the NASS Help Desk at 1-888-650-0822 for assistance.		
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Click the Save Completed Steps button if you want to save this page BEFORE completing all 5 steps – that is, if you have checked the Step Completed box for some, but not all steps. Please note: Clicking on this button will **not** submit your data for the CDC annual report.

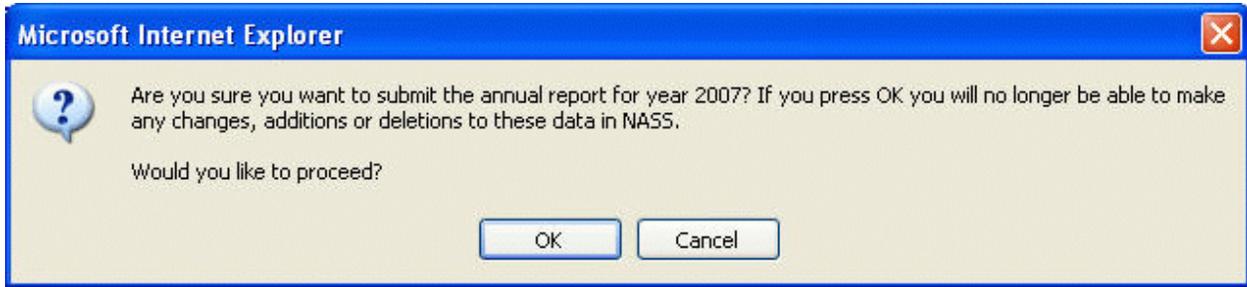
Save Completed Steps

Click on the button below to submit your final data for the annual CDC ART Success Rate Report

Submit Final Annual Data

Click here to submit your final annual data

After clicking on this button, you will see a pop-up box on the screen asking if you are sure that you want to submit the data (see next page). Click OK if you want to continue with the submission.



If you have not completed all four previous steps and checked off all the Step Completed boxes, you will see a pop up message like the one below telling you which step has not been

Step 4	Section 4	<p>After completing Steps 1-3, run the Annual Submission Clinic Table to review. If any data are inaccurate, corrections must be made in NASS. Handwritten corrections to data on this report will not be accepted. This table can be rerun until data are ready for submission.</p> <p>The Medical Director must sign off on the final hardcopy clinic table and forward this document to Westat with other annual submission materials.</p>	Annual Submission Clinic Table	<input type="checkbox"/>
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A Microsoft Internet Explorer error dialog box with a blue title bar and a yellow warning icon. The text inside reads: "Step 4 has NOT been marked as completed. Data cannot be submitted until all checkboxes have been checked." There is an "OK" button at the bottom.

marked as completed.

Once you have successfully submitted your annual data, the Step Completed check boxes on the screen will become read-only as well as the cycle data that you submitted for this reporting year. If you discover an error after your final data submission, please contact the NASS Help desk for assistance at 1-888-650-0822 or NASS@Westat.com.

Appendix 1 - NASS Screen Shot of the Submit Annual Data Web Page

Reporting Year 2007 is open for data entry

Prior to submitting your reporting year data, please follow the steps below. After completing each step, click on the "Step Completed" box on the right side of the table to indicate that the step has been performed. For your convenience, we have provided the ability to run reports that will assist you in completing each step. Before you begin the process, please check to ensure that the reporting year for which you are submitting data is the one shown in the title of this screen.

Refer to the NASS Annual Submission Guide for further details and instructions for each step listed below. The guide is posted in NASS under the left-hand side menu item Clinic Profile & Data, in the Submission Guide sub-menu. You may also contact the NASS Help Desk at 1-888-650-0822 for assistance.

Step	Annual Submission Guide Section	Step Description	Run Report	Step Completed
Step 1	Section 1	Print the Annual Current Clinic Profile report to check that clinic profile & services data, current clinic name and address, lab information, Medical Director name and degrees, and organization status are complete and accurate as they should appear in the annual report.	Annual Current Clinic Profile	<input type="checkbox"/>
Step 2	Section 2	Check for open cycles in this reporting year by running the Annual Open Cycle Report. All cycles must be marked "Complete" in NASS to be included in NASS reports and in the CDC annual report. Open cycles must be resolved in NASS prior to moving on to Step 3. This report should be rerun until it indicates that there are no more open cycles for this reporting year.	Annual Open Cycles Report	<input type="checkbox"/>
Step 3	Section 3	After completing Step 2, run the Comprehensive Edit Report to review a list of all inconsistent and unlikely cycle data. Please note that the only cycles shown on this report are ones marked "Complete" in NASS (see Step 2). Inconsistent data must be corrected in NASS prior to printing the Annual Submission Clinic Table. Unlikely cycle data should be reviewed to ensure that they are accurate, and corrected in NASS if not. This report must be rerun until all inconsistent data have been corrected in NASS and unlikely data have been reconciled or confirmed. Handwritten notes on the last run of the Comprehensive Edit Report may be made to indicate that remaining unlikely data have been confirmed by the clinic. Please note that handwritten <u>corrections</u> to data on this report will not be accepted. All data changes must be made in NASS. The clinic Data Manager (or Medical Director) must sign off on the final hardcopy of the report and forward this document to Westat with other annual submission materials.	Comprehensive Edit Report	<input type="checkbox"/>
Step 4	Section 4	After completing Steps 1-3, run the Annual Submission Clinic Table to review. If any data are inaccurate, corrections must be made in NASS. Handwritten corrections to data on this report will not be accepted. This table can be rerun until data are ready for submission. The Medical Director must sign off on the final hardcopy clinic table and forward this document to Westat with other annual submission materials.	Annual Submission Clinic Table	<input type="checkbox"/>
Step 5	Section 5	After Steps 1-4 have been performed, and the Annual Submission Clinic Table is final, click on the Submit Final Annual Data button below to submit your final data for publication. Please note that once you have submitted your final data, you will no longer be able to make any changes, additions or deletions to these data in NASS. However, you may continue to view data in NASS for this reporting year. If you discover an error after data submission, please contact the NASS Help Desk at 1-888-650-0822 for assistance.		

Click the Save Completed Steps button if you want to save this page BEFORE completing all 5 steps – that is, if you have checked the Step Completed box for some, but not all steps. Please note: Clicking on this button will **not** submit your data for the CDC annual report.

Save Completed Steps

Click on the button below to submit your final data for the annual CDC ART Success Rate Report

Submit Final Annual Data

Submit all signed hardcopy annual submission materials and lab certificate(s) to:
NASS Processing Center
Westat
1450 Research Boulevard, Room TC1021F
Rockville, MD 20850-3195
Phone (if required by overnight courier): 1-888-650-0822

Appendix 2

Minimum Clinic Data Required in NASS to Complete Step 1

NASS Screen	Screen Section	Clinic Data Variable	Notes	Required Fields for Reorganized and Closed Clinics
Name&Address	Reporting Year Clinic Name	<ul style="list-style-type: none"> • Name 1 • City • State 	Name 2 should be included if applicable	√
Name&Address	Current Clinic Information	<ul style="list-style-type: none"> • Status • Name 1 • Address 1 • City • State • Zip code • Phone • Fax 	Name 2 and Address 2 should be included if applicable	√
Key Staff	Medical Director	<ul style="list-style-type: none"> • First Name of Medical Director • Last Name of Medical Director • Degree(s) of Medical Director 		√
Services&Profile	Services and Profile	<ul style="list-style-type: none"> • SART Member • Gestational carriers services • Single women services • Donor egg program • Donor embryo program • Embryo freezing offered 		
Lab&Certification	Current Embryo Lab Information	<ul style="list-style-type: none"> • Name 1 • CAP accredited (yes/no/pending) • JCAHO accredited (yes/no/pending) • NYSTB accredited (yes/no/pending) 	These data variables must be complete for all embryo labs used by a clinic	

Appendix 3

Example of Annual Current Clinic Profile Report

Report-A01 (09/15/2008): Annual Current Clinic Profile

Clinic ID: 1023 SART ID: Reporting Year: 2007

Reporting Year Name and Location for Top of Clinic Page

NEAR NORTH CLINIC

MINNEAPOLIS, MINNESOTA

Current Medical Director

Data verified by:

Ronald P. Art, MD

Current Clinic Information for CDC Report Appendix

Current Name Status = Same as reporting year name

Near North Clinic

100 Main Street

Minneapolis, MN 55414

Telephone: (555) 555-1234

Fax: (555) 555-4567

Lab Name: Near North Laboratory

Lab Address: 100 Main Street

Suite 100

Minneapolis, MN 55414

Telephone: (555) 555-1212

Fax: (555) 555-1313

Accreditation:

- CAP/ASRM
- JCAHO(pending)

Report-A01 (09/15/2008): Annual Current Clinic Profile
Clinic ID: 1023 SART ID: Reporting Year: 2007

Current Clinic Services and Profile

Current Name Status = Same as reporting year name

Current Name: Near North Clinic

Donor eggs? Yes

Donor embryo? Yes

Single women? Yes

Gestational carriers? Yes

Cryopreservation? No

SART member? No

Appendix 4

Example of Annual Open Cycle Report

Report-A02 (09/15/2008): Annual Open Cycle Report

Open Cycles for Clinic 1023 in Reporting Year 2007

Reporting Name: Near North Clinic

Listing is ordered by Patient ID

Patient ID	Date of Birth	Optional ID 1	Optional ID 2	Patient Cycle Number	Cycle Start Date
1023-10000-1	01/01/1980	abc		1	02/25/2007
1023-10000-1	01/01/1980	abc		2	01/05/2007
1023-10000-1	01/01/1980	abc		3	
1023-10000-1	01/01/1980	abc		4	01/18/2007
1023-10000-1	01/01/1980	abc		5	02/14/2007
1023-10000-1	01/01/1980	abc		6	02/18/2007
1023-10004-9	11/25/1970	DIA	Test	8	

Appendix 5

Sample Page From the Comprehensive Edit Report

NASS Comprehensive Edits Report (09/15/2008)

Clinic 1023

Reporting Year 2007

Signature of reviewer (e.g., Data Manager, Medical Director): _____

Clinic Edits

*****MANDATORY TO FIX***** Data issues that have to be corrected:		
EditID	Screen	Message
E1299	Key Staff	You must enter the first name, last name, and degrees for each of the following key staff members: Medical Director, Practice Director and Lab Director. At least one of these items has been left blank. Note for the Medical Director Degree: at least MD or DO must be selected. Please complete data entry in the Clinic Profile, Key Staff screen. (Edit 1299)

Patient Edits

Potential duplicate cycles have been detected that have the same cycle start date and Patient ID. If patient's cycle intent changed (fresh --> frozen), check the data definitions to ensure the correct cycle start date for the corresponding cycle is being reported. (Edit E1373)					
Patient ID	Optional Identifier 1	Optional Identifier 2	Date of Birth	Cycle ID	Cycle Start Date
1023100049	DIA	Test	11/25/1970	2	02/02/2007
1023100049	DIA	Test	11/25/1970	5	02/02/2007

Patient ID: 1023100025 Cycle ID: 1 *****MANDATORY TO FIX***** Data issues that have to be corrected:		
EditID	Screen	Message
E1024	Demographics	You must enter a value for "Primary residence in U.S.". (Edit E1024)
E1058	History	On the Patient History II screen, you must either check that FSH is unknown or enter a value in the "Patient Maximum FSH" box. If you have entered a value in the "Patient Maximum FSH" box, then you must either check that the Lab upper normal FSH is unknown or enter a value in the Lab upper normal FSH box. (Edit E1058)
E1066	History	You must enter a Reason for ART on the Patient History II screen. (Edit E1066)

Appendix 6

Sample Template of Annual Clinic Submission Table

NEAR NORTH CLINIC MINNEAPOLIS, MINNESOTA

Medical Director signature: _____

A comparison of clinic success rates may not be meaningful because patient medical characteristics and treatment approaches vary from clinic to clinic. For more details about this, along with information on how to interpret the statistics in this table, see pages ##-##.

2007 ART CYCLE PROFILE							
Type of ART (a)				Patient Diagnosis			
IVF	67%	Procedural Factors:		Tubal factor	0%	Other factor	0%
GIFT	0%	With ICSI	0%	Ovulatory dysfunction	0%	Unknown factor	0%
ZIFT	0%	Unstimulated	33%	Diminished ovarian reserve	0%	Multiple Factors:	
Combination	33%	Used gestational carrier	17%	Endometriosis	0%	Female factors only	0%
		Used PGD	17%	Uterine factor	0%	Female & male factors	25%
				Male factor	13%		

2007 PREGNANCY SUCCESS RATES					Data verified by Ronald P. Art, MD				
Type of Cycle			Age of Woman						
Fresh Embryos from Nondonor Eggs			<35	35-37	38-40	41-42 (d)			
Number of cycles			1	4	1	0			
Percentage of cycles resulting in pregnancies (b)			0/1	0/4	0/1				
Percentage of cycles resulting in live births (b,c)			0/1	0/4	0/1				
(Confidence Interval)									
Percentage of retrievals resulting in live births (b,c)			0/1	0/2	0/1				
Percentage of transfers resulting in live births (b,c)				0/2					
Percentage of transfers resulting in singleton live births (b)				0/2					
Percentage of cancellations (b)			0/1	2/4	0/1				
Average number embryos transferred				4.0					
Percentage of pregnancies with twins (b)									
Percentage of pregnancies with triplets or more (b)									
Percentage of live births having multiple infants (b,c)									
Frozen Embryos from Nondonor Eggs			<35	35-37	38-40	41-42 (d)			
Number of transfers			0	0	0	0			
Percentage of transfers resulting in live births (b,c)									
Average number of embryos transferred									

Donor Eggs	All Ages Combined (e)	
	Fresh Embryos	Frozen Embryos
Number of transfers	0	0
Percentage of transfers resulting in live births (b,c)		
Average number of embryos transferred		

CURRENT CLINIC SERVICES AND PROFILE			
Current Name: Near North Clinic			
Donor egg?	Yes	Gestational carriers?	Yes
		SART member?	No
Donor embryo?	Yes	Cryopreservation?	No
		Verified lab accreditation?	Yes
Single women?	Yes	(See Appendix C for details.)	

- (a) Reflects patient and treatment characteristics of ART cycles performed in 2007 using fresh nondonor eggs or embryos. 09/15/2008
 (b) When fewer than 20 cycles are reported in an age category, rates are shown as a fraction and confidence intervals are not given. Calculating percentages from fractions may be misleading and is not encouraged.
 (c) A multiple-infant birth is counted as one live birth.
 (d) Clinic-specific outcome rates are unreliable for women older than 42 undergoing ART cycles using fresh or frozen embryos with nondonor eggs.