

3501: Pregnancy Form

This form captures information regarding a female recipient's or a male recipient's female partner's pregnancy. This form must be completed when a pregnancy is reported on a Cellular Therapy Essential Data Follow-Up (4100) or Post-Infusion Follow-Up (2100) Form. The Pregnancy (3501) Form will also have the option to be created on-demand (on-demand is when a form can be generated at any time). Centers are encouraged to generate this form on-demand as soon as it is known that a female recipient or a male recipient's female partner is pregnant. This form is used to capture information regarding pregnancies following HCT or cellular therapy infusions.

One Pregnancy (3501) Form must be completed for each pregnancy and is designed to capture the estimated delivery date, the outcome of the pregnancy and the delivery date. If the form was created using the on-demand function and the female recipient or the male recipient's female partner is pregnant at the time of submitting this form, submit the form and report the outcome of the pregnancy on the same form. If the form came due as a result of reporting a pregnancy on the Cellular Therapy Essential Data Follow-Up (4100) or Post-Infusion Follow-Up (2100) Form and the female recipient or the male recipient's female partner is pregnant on the reported contact date for the current reporting period, submit the form and return to complete the same form when the outcome of the pregnancy is known. This will ensure that all data corresponding to each pregnancy is correctly captured on the same form.

Links to Sections of Form:

[Q1 – 6: Functional Status](#)

Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please reference the retired manual section on the [Retired Forms Manuals](#) webpage

Date	Manual Section	Add/ Remove/ Modify	Description
1/22/ 2021	3501: Pregnancy Form	Add	Version 1 of the 3501 Pregnancy Form section of the Forms Instructions Manual released. Version 1 corresponds to revision 2 of the Form 3501.

Last modified: Feb 14, 2023

Q1-6: Functional Status



If the female recipient or the male recipient's female partner is pregnant at the time of submitting this form (created on-demand) or is pregnant on the reported contact date for the current reporting period (created as a result of reporting a pregnancy on the Cellular Therapy Essential Data Follow-Up (4100) form), submit the form and return to update the form when the outcome of the pregnancy is known.

Question 1: Estimated delivery date

Report the estimated delivery date, as documented within the medical record. If the date is not documented, seek physician clarification.

Question 2: Was the recipient pregnant at the time of this report? (Female only)

Indicate Yes or No if the recipient (female only) was pregnant at the time of completing this form.

If this form was created using the on-demand function, indicate if the recipient is pregnant at the time of submitting this form.

If this form was generated as a result of reporting on the Cellular Therapy Essential Data Follow-Up (4100) form, indicate if the recipient is pregnant on the contact date for the corresponding reporting period in which the pregnancy was first reported.

If the recipient is pregnant at the time of completing this form (on-demand) or pregnant on the reported contact date for the current reporting period, select Yes and submit the form.

Question 3: Was the recipient's female partner pregnant at the time of this report (Male only)

Indicate Yes or No if the male recipient's female partner was pregnant at the time of this report.

If this form was created using the on-demand function, indicate if the male recipient's female partner is pregnant at the time of submitting this form.

If this form was generated as a result of reporting on the Cellular Therapy Essential Data Follow-Up (4100) form, indicate if the male recipient's female partner is pregnant on the contact date for the corresponding reporting period in which the pregnancy was first reported.

If the male recipient's female partner is pregnant at the time of completing this form (on-demand) or pregnant on the reported contact date for the current reporting period, select Yes and submit the form.

Question 4: Specify the outcome of the pregnancy

Indicate the outcome of the pregnancy. The Unknown option should be used sparingly and only when no

information can be obtained regarding the outcome.

If the outcome of the pregnancy is either Live birth, at term or Live birth, premature, continue with question 5.

If the outcome of the pregnancy is either Intrauterine fetal death, Spontaneous abortion, Elective abortion or Unknown, submit the form.

Question 5: Were there congenital abnormalities? (Live birth)

Congenital abnormalities are defined as structural or functional abnormalities that occur during intrauterine life.

Examples of structural abnormalities include cleft palate, club foot, missing or abnormal limbs, etc.

Examples of functional abnormalities include mental retardation, Down syndrome, etc.

Indicate Yes or No if the baby was diagnosed with a structural or functional congenital abnormality(ies).

Questions 6: Delivery date

Specify the date of delivery. If the exact delivery date is not known but the month and year is known, use the process described for reporting partial or unknown dates in the [General Instructions, Guidelines for Completing Forms](#) and select the Date estimated box.

Signature Lines:

The FormsNet3SM application will automatically populate the signature data fields, including name and email address of person completing the form and date upon submission of the form.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jan 22, 2021