

Submitting a Product Complaint to NMDP Using FormsNet3SM – Quick Reference

The Product Complaint Form (Form 3010) should be submitted if the integrity of a cellular product is compromised at receipt or at any time thereafter, unless the incident was clearly the result of a transplant center action. The transplant center should submit this form if any of the following apply to a distributed product:

- The product has transmitted or may have transmitted a relevant communicable disease to the recipient (FDA-defined: HIV 1/2, HBV, HCV, HTLV I/II, CJD, syphilis, vaccinia, and WNV; and NMDP-defined: Chagas)
- Product problem relating to the potential for transmission of relevant communicable disease, such as the failure to comply with cGTP requirements. [21 CFR 1271.3(aa)]
- Failure to meet product specifications, impacting the safety, quality, identity, purity, or potency (SQIP) of the product

Some additional reasons to submit a product complaint form include: a broken unit, compromised shipping conditions, a contaminated product, positive product culture, or incorrect labeling.

This may be discovered by the transplant center at:

- Receipt
- Thaw, if applicable
- Processing
- Infusion
- After infusion

This form should be completed as soon as possible after identifying the problem and must be completed within three working days of the institution becoming aware of the event.

To log on, go to <https://formsnet3.nmdp.org>.

- Provide your NMDP username.
Usually first initial plus up to 7 letters of your last name
- Enter your password for FormsNet3 (LDAP)

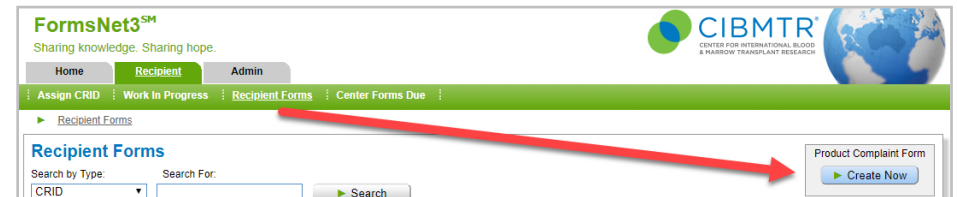
If you are using Okta Verify:

- Click “Send Push Notification”
- Approve the push notification on your mobile device.

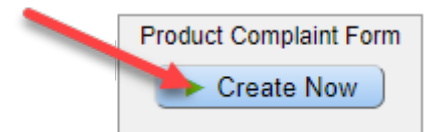
If you are using an RSA SecurID token (hard or soft):

- Enter your username
- Enter your PIN+6 digits from the SecurID device (or only the 8 digits from your mobile device if using a soft token.)

- Once logged into FormsNet3 Click on Recipient at the top of the screen
- On the left side of the green menu bar in FormsNet3SM, click on the third item for Recipient Forms.



- On the right side under Product Complaint Form click on “Create Now”



- Confirm that you want to create a Product Complaint Form by clicking “Yes”

