POLICY

POLICY STATEMENT

It is the policy of the National Marrow Donor Program/Be The Match (NMDP) that operational documents such as manuals of operation, SOPs, policies, forms, etc., are released to NMDP network partners on a quarterly basis, and that 60 days prior notice of changes will be provided whenever possible.

BUSINESS SECTION/DEPARTMENT

This policy applies to all departments who provide documents to network partners via the Be The Match Clinical Network website:

- Donor & Collection Services
- Provider Services
- CIBMTR
- Quality Assurance and Regulatory Affairs (QARA)

PURPOSE

This policy clarifies standard practices related to provision of operational documents to NMDP network partners, including donor centers, apheresis and collection centers, and transplant centers.

SCOPE

This policy applies to NMDP documents related to operational processes at network centers, where network centers are expected to implement or update internal processes and/or documents.

Exceptions to this policy may include documents which are developed and approved by an Institutional Review Board (IRB), require HRSA or other government agency approval, or are otherwise outside of the direct control of NMDP operations departments. While such exceptions will exist, efforts will be made to align any of these document changes with the quarterly schedule whenever possible.

RELATED DOCUMENTS

Not applicable

DEFINITIONS

Not applicable
RESPONSIBILITIES

Designated Donor Services, Provider Services, QARA, and CIBMTR staff are responsible for collaboratively establishing and publishing the quarterly release calendar on an annual basis.

NMDP leaders in Donor & Collection Services, Provider Services, and CIBMTR are responsible for approving the release calendar.

Audience owners in Donor & Collection Services, Provider Services, and CIBMTR are responsible for approving any exceptions to this policy.

REQUIREMENTS

1. NMDP will establish and publish annual quarterly release dates for network-facing documents. This schedule will be available and visible to network partners as well as internal NMDP staff.

2. NMDP will provide draft documents to the network 60 days prior to required implementation date whenever possible to allow partners to make internal changes.

3. Standard exceptions to the quarterly release and/or 60 day advance notice requirements will include:
   - Changes driven by FDA or other government agency announcement with implementation deadlines determined by the government agency (e.g., emerging disease impacts to donor eligibility assessments).
   - Minor changes to forms and/or job aids where network partners are expected to use NMDP original documents. (Examples include reference tables or correction of typographical errors or form functionality issues.)
   - Documents approved and issued by an IRB.

4. Any other exceptions to the quarterly release calendar must be approved by the audience owner(s) for the impacted partners.

5. Changes will be clearly communicated to network partners through the Network Announcement process.

   5.1. Announcements will include a summary of changes, including reason for changes; a link to redlined or watermarked document providing specific detailed changes; and a clear description of the expected impact to each network center type (e.g., an AC may need to implement a process change while a TC only needs to be aware of the change happening elsewhere).

REFERENCES

NMDP Network Center Participation Agreement
REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision</th>
<th>Brief Description of Revision</th>
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<tr>
<td>P00108</td>
<td>New Policy</td>
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ADDENDA

Not applicable