ASHI appreciates the efforts by the NMDP to amend the NMDP-CT policy with the goal of improving patient HCT outcomes. ASHI has some comments/concerns related to the proposed policy changes.

NMDP requirement:

Genotypes: the reported high-resolution HLA typing results must meet one of the following two criteria:

1. Must contain only one unambiguously assigned genotype or
2. May contain multiple genotypes if one includes two CI and the others do not include any alleles listed as CI. No distinction is made between common (C) and infrequent (I) in the policy.

Exceptions must be submitted and approved by NMDP clinical HLA services. Timely submission will ensure prompt approval without delay in the search process.

ASHI comment: There are many HLA laboratories that use sequence-based typing technologies that may not be able to resolve some of these ambiguities. There is concern that requiring submission and approval from the NMDP before proceeding will unnecessarily burden institutions with devoting extra time and resources to this process and possibly delay transplant for patients in need, since the turnaround time for approval is not stated. In addition, because the new CIWD version 3.0.0 reference will not be released until later this year, it prevents labs from assessing the impact this will have to ambiguity resolution at the current time.

NMDP requirement:

Form 22/117 should be electronically submitted. For TCs who are submitting the forms manually, NMDP will collaborate with TC's testing lab to achieve electronic submission.

ASHI comment: ASHI agrees with the goal of universal electronic submission of data to reduce risk of clerical error and enhance efficiency, however, labs who manually submit may have limitations to electronic reporting that are beyond their control:

1. There are limitations to some electronic reporting platforms that bypass director review prior to submission. Several laboratories are concerned with this issue and have elected not to electronically submit until the problem is corrected.
2. Implementation of electronic reporting may be held up by institutional barriers such as LIS resources and budget restrictions.

NMDP requirement:

Typing assignments obtained at the time of donor recruitment do not replace HLA-CT on a second independent sample.

ASHI comment: While this is not a policy change, members of the ASHI National Clinical Affairs Committee request statistics from the NMDP for future consideration. ASHI would like to evaluate the occurrence of disparate typing (i.e. typing that results in a mismatch in the antigen binding site) on donors in the registry who already have high resolution sequence-based typing at the required HLA loci. There is concern that high-resolution HLA-CT may not be warranted on registry donors who already have documented sequenced-based typing. Possibly low-resolution confirmation on these donors may be sufficient for this purpose.