

## Canadian Blood Services Leukoreduced Whole Blood Program for Non-Military Use

Canadian Blood Services will be expanding the Leukoreduced Whole Blood Program to make the component available for non-military customers.

Leukoreduced whole blood (LrWB) has not been shown to be superior to conventional blood components (packed red blood cells, plasma, platelet concentrates) and, per NAC recommendations, production of conventional blood components will be prioritized over LrWB.

Hospitals interested in obtaining LrWB can submit an application describing the study to Canadian Blood Services. For approval, the proposed study should:

1. Be a prospective clinical study<sup>1</sup>
2. Have a clinically relevant primary outcome (e.g. mortality, time in hospital, number of transfusions, etc.)
3. Use LrWB to treat clinically significant bleeding **or** have been approved by Health Canada for off-label use
4. Be registered with a recognized study registry (e.g. United States National Library of Medicine [clinicaltrials.gov], EudraCT [EU Clinical Trials Register], ISRCTN, WHO Registry Network)
5. Have peer-reviewed grant funding
6. Have a plan for handling LrWB units that are approaching expiration, including specific indications and patient populations if that plan is to use off-study to avoid waste
7. Monitor off-study LrWB use and adjust ordering as needed<sup>2</sup>
8. Have a process for documenting all non-study LrWB transfusions and recording location of transfusion, indication, recipient ABO/Rh group, and clinical outcome<sup>3</sup>
9. Report the disposition of all issued units of LrWB, including the number of units transfused on- and off-study, indications for transfusion
10. Require quantities of LrWB that Canadian Blood Services anticipates being able to provide (if not currently, in future)<sup>4</sup>

- <sup>1</sup> Priority will be based on methodologic quality pending available inventory
- <sup>2</sup> Programs are expected to adjust ordering monthly to ensure off-study use of LrWB and expiry is minimized
- <sup>3</sup> Hospitals are asked to report non-study transfusions via the NAC-supported registry
- <sup>4</sup> Approved Studies will be supported on a first-come, first-serve basis. As needed, eligible studies will be waitlisted until support is possible. Simultaneous studies will be prioritized based on study methodology, study endpoints, and anticipated practice impact.