

***Fiscal Year 2020 Department of Defense Reconstructive Transplant Research Program (RTRP)  
Reference Table of Award Mechanisms and Submission Requirements***

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadlines
<p><b>Investigator-Initiated Research Award</b></p> <p>Go to:</p> <ul style="list-style-type: none"> <li>• Program Announcement</li> <li>• General Application Instructions</li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b> W81XWH-20-RTRP-IIRA</p>	<p>Independent investigators at all academic levels (or equivalent).</p>	<ul style="list-style-type: none"> <li>• Supports studies with the potential to make an important contribution to the reconstructive transplant research field, patient care, and/or quality of life.</li> <li>• <b><i>Preproposal is required; full application submission is by invitation only.</i></b></li> <li>• <b><i>Preliminary or published data are required.</i></b></li> <li>• Applications must address at least one of the FY20 RTRP Investigator- Initiated Research Award Focus Areas: <ul style="list-style-type: none"> <li>○ <b>Reduce the risks of VCA-associated immunosuppression</b> <ul style="list-style-type: none"> <li>▪ Define the unique mechanisms of VCA immunogenicity.</li> <li>▪ Develop novel approaches for improving VCA immune tolerance.</li> <li>▪ Identify unique immunosuppression requirements for VCA compared to other solid organ transplants.</li> </ul> </li> <li>○ <b>Develop reliable non-invasive methods or tools for monitoring VCA graft rejection</b> <ul style="list-style-type: none"> <li>▪ Develop reliable non-invasive biomarkers for monitoring chronic VCA graft rejection in a large animal model.</li> <li>▪ Identify and/or validate new peripheral biomarkers for acute and chronic rejection.</li> <li>▪ Develop assays or devices for clinical graft monitoring utilizing validated biomarkers.</li> </ul> </li> <li>○ <b>Advance existing or develop innovative ex vivo tissue preservation strategies to extend the timeline between procurement and transplantation</b> <ul style="list-style-type: none"> <li>▪ Develop novel approaches and models for perfused, hypothermic, high subzero and low subzero, or static preservation strategies.</li> <li>▪ Determine the extent to which VCA tissue preservation technology impacts VCA immunogenicity.</li> </ul> </li> </ul> </li> <li>• <b>Multiple PI Option:</b></li> <li>• Supports synergistic partnerships among two to four investigators collaborating on a single application; multi-institutional collaborations are encouraged.</li> </ul>	<p><b>Single PI:</b></p> <ul style="list-style-type: none"> <li>• Maximum funding of <b>\$1 million (M)</b> for total costs (direct plus indirect costs).</li> <li>• Maximum period of performance is <b>3</b> years.</li> </ul> <p><b>Multiple PI Option:</b></p> <ul style="list-style-type: none"> <li>• Maximum total funding of <b>\$1.5M</b> for total costs (direct plus indirect costs).</li> <li>• Maximum period of performance is <b>3</b> years.</li> </ul>	<p><b>Preapplication (Preproposal):</b> August 19, 2020 5:00 p.m. Eastern time</p> <p><b>Application:</b> November 12, 2020 11:59 p.m. Eastern time</p>

<p><b>Clinical Network Award</b></p> <p>Go to:</p> <ul style="list-style-type: none"> <li>• Program Announcement</li> <li>• General Application Instructions</li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b> W81XWH-20-RTRP-CNA</p>	<p>Independent Investigators at or above the level of Assistant Professor (or equivalent) are eligible to be named PI.</p>	<ul style="list-style-type: none"> <li>• To promote a major multi-institutional network of VCA Centers and associated collaborators for the purpose of standardizing clinical protocols and SOPs for face and hand transplantation, and assessing and validating those protocols and SOPs in multi-institutional clinical trials.</li> <li>• This effort will be executed through a two-phased approach in the form of a single award to the Clinical Network Coordinating Center. The Coordinating Center will serve as the Clinical Network information and planning nexus, providing administrative, operational, and data management support services to implement Clinical Network activities in a timely manner. <ul style="list-style-type: none"> <li>○ <b>Phase 1 Objectives</b> <ul style="list-style-type: none"> <li>▪ Establish the Clinical Network</li> <li>▪ Develop standardized protocols and SOPs</li> <li>▪ Develop Clinical Trial Applications</li> <li>▪ Coordinate external Peer Review</li> <li>▪ Obtain all regulatory approvals</li> </ul> </li> <li>○ <b>Phase 2 Objectives</b> <ul style="list-style-type: none"> <li>▪ Conduct clinical trials (one for face transplantation, and one for hand transplantation)</li> </ul> </li> </ul> </li> <li>• <b>Submission of a Letter of Intent is <i>required</i> prior to full application submission.</b></li> <li>• <b><i>FY20 RTRP Clinical Network Award Focus Areas:</i></b> Must address the standardization, assessment, and validation of protocols and/or standard operating procedures (SOPs) for each of the following aspects of VCA for face and hand transplantation: <ul style="list-style-type: none"> <li>○ Patient inclusion/exclusion criteria</li> <li>○ Patient education</li> <li>○ Surgical procedures</li> <li>○ Immunosuppression and/or immunoregulation</li> <li>○ Outcome metrics</li> <li>○ Quality of life measures</li> <li>○ Rehabilitation</li> <li>○ Patient reporting (e.g., registry)</li> </ul> </li> </ul>	<p><b>Phase 1:</b></p> <ul style="list-style-type: none"> <li>• Maximum funding of <b>\$3 million (M)</b> for total costs (direct plus indirect costs).</li> <li>• Phase 1 funds will be awarded in <b>FY20</b>.</li> <li>• Maximum period of performance is <b>2</b> years.</li> </ul> <p><b>Phase 2:</b></p> <ul style="list-style-type: none"> <li>• Maximum funding of <b>\$10M</b> for total costs (direct plus indirect costs).</li> <li>• Phase 2 funds are anticipated to be awarded in <b>FY22</b>, pending availability of funds and successful completion of Phase I objectives.</li> <li>• Maximum period of performance is <b>4</b> years.</li> </ul>	<p><b>Pre-Application (Letter of Intent):</b> November 17, 2020 5:00 p.m. Eastern time</p> <p><b>Application:</b> December 3, 2020 11:59 p.m. Eastern time</p>
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