Variance Application

For UNOS Use Only	
Date Submitted to UNOS:	Date Implemented:
Date Committee Reviewed:	Date of Next Review:
Date Circulated for Public Comment:	Date of Termination:
Date Board Approved:	Org. Code(s)

1. Participant Information and Intent for Variance

a. Submitting Members:

A variance may be submitted by one or more Members (OPO, transplant center, etc).List the Members that are submitting the proposed variance.

b. Will this application require other Members to join the proposed variance? If so, list them and whether they support the application.

Ex. If a Transplant Hospital applies for a variance that covers their entire DSA, all of the Transplant Hospitals in the DSA must be listed below.

Member	Org. Code	Support	
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No

If any Member required to participate in the proposed variance does not support the variance, you must submit signed statements from each participant. This application will not be considered unless it receives affirmative support from at least 75% of the Members required to join it.

c. This request is to (select one from each column):

☐ Create
☐ Extend
☐ Amend
☐ Withdraw from
☐ Terminate
☐ Join

☐ An AAS
☐ A Sharing Agreement
☐ An ALU
☐ An Alternative point assignment system
☐ Other _____

You do not need to complete the remainder of this form if this is an application to participate in an existing, open variance. You may need to submit additional information as specified in the particular open variance you wish to join.

d. This request is to alter or continue to alter the following national allocation algorithms (select all that apply):

Submit revised allocation algorithm(s).

- ☐ Heart
- ☐ Lung
- ☐ Heart/Lung
- ☐ Kidney
- ☐ Pancreas
- ☐ Kidney/Pancreas
- ☐ Liver
- ☐ Liver/Intestine
- ☐ Not Applicable

e. The goals of this proposal are to (select all that apply):

A variance application must include objective, measurable goals.

- ☐ improve efficiency of organ placement
- ☐ improve patient or graft survival
- ☐ facilitate organ procurement
- ☐ Increase broader sharing of organs for allocation/distribution
- ☐ insert other _____

f. Explain why the current, national allocation system does not sufficiently address the needs of the transplant professionals or candidates that your organization serves.

Submit additional data or evidence to support your claim as Attachment C to this application; anecdotal information is not sufficient.

g. Submit policy language

Submit policy sections that this variance alters and proposed modifications to those sections.

h. Is this an open variance? If so, you must include the criteria and timeframe for other Members to join.

- ☐ Yes, this is an open variance.
- ☐ No, this is a closed variance.

2. Research and Evaluation Plan

The OPTN Final Rule requires that variances must include a research design, data collection plan, and analysis plan. Furthermore, the Final Rule states that variances must be time limited.

a. What is the target audience/population?

Which group or groups of individuals will this proposal benefit?

b. This variance will expire (select one):

- ☐ After one year of operation
- ☐ After two years of operation
- ☐ After three years of operation
- ☐ After four years of operation
- ☐ On _____ (date)

c. The following data elements will be used to evaluate this variance:

List each data element according to its UNet℠ field label. A description of the file layouts for the Waitlist and TIEDI forms are on UNet℠. Indicate new data fields with an asterisk (*).

Field Name	Description	Level	Frequency

d. Explain how these data elements will be used in implementing and evaluating the variance.

e. The predicted outcomes from this variance include:

Predict the outcome indicators for each checked goal in section 1.e.

Instructions and Background

Application for Approval or Modification of a Variance

Application Contact Information

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Purpose of this Instruction Document

This document provides background information about variance and instructions for completing the accompanying application to create, amend, withdraw from, terminate, or join a variance.

Glossary of Terms

Term	Definition
Alternative Allocation System (AAS)	a type of variance that allows Members to allocate organs differently than the standard allocation system requires for that organ
Alternative Local Unit (ALU)	a type of variance that creates distinct geographic areas that function as distinct areas for organ procurement and distribution.
Alternative Point Assignment Systems	a type of variance that permits Members to assign points differently than the OPTN policies
Closed Variance	a variance not open for other Members to join it
Local Unit	the geographic area for organ procurement and distribution
Open Variance	a variance that allows other Members to join it
Sharing Arrangement	a type of variance that permits two or more OPOs to share organs
Variance	an experimental policy that tests methods of improving allocation

When to Apply for A Variance

When a policy characteristic or a set of policy characteristics of the national organ allocation system no longer satisfactorily addresses the transplantation needs of the local unit's community, then this local unit may consider developing a proposal for a variance. The purpose of the proposed variance could be to improve organ availability, organ quality, organ distribution, or organ allocation in the community served by the local unit. These improvements may be in the areas of organ utilization, equity regarding

to whom organs are distributed, or ameliorating problematic geographic characteristics of the local unit. A variance proposal might also aim to achieve one or more of the program goals identified by the Health and Human Services Administration (HHS).

At a high level, the proposal for a variance should clearly explain the need for the variance, how the variance differs from the current allocation system, how the proposed variance would benefit the community served by the local unit, and how the local unit will evaluate the impact of the proposed variance.

Types of Variances and References

The HHS Final Rule 121.8(g) provides the framework for all variances:

> […] (g) Variances. The OPTN may develop, in accordance with §121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of §121.4. […]

The OPTN/UNOS policies recognize several types of variances that can alter the national allocation system for a given local unit:

- Alternative allocation systems
- Alternative local units
- Sharing arrangements
- Alternative point assignment systems

OPTN/UNOS Policy 3.4 provide details on the experimental design methodology prescribed by the Final Rule, the proposal submission process, and data submission requirement.

While the variance application form that accompanies this instruction document outlines the proposal submission requirements, completing this application will require referencing polices and the Final Rule section cited above. In addition, the applicant should address any organ-specific policies as relevant (Policies 3.5 through 3.11) and the following HHS Program Goals:

1. Increase the number of deceased donor organs transplanted each year until 42,800 are transplanted in 2013.
2. Increase the number of non-DCD donors each year until 9,251 is achieved in 2013.
3. Increase the number of DCD donors each year until 2,018 is achieved in 2013.
4. Increase the average number of organs transplanted per non-DCD donor each year by 0.080 to reach 4.0 in 2013
5. Increase the average number of organs transplanted per DCD donor each year by 0.096 to reach 3.0 in 2013.

Click on the following link to read the policies referenced above:
http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp.

Variance Submission and Approval Process

The applicant should submit a variance application to the relevant Committee. Since all variances are variations of OPTN/UNOS policy, the sponsoring Committee for a variance should be the same Committee that would normally approve amendments to the underlying policy section.

Once submitted, the variance approval timeline will coincide with Committee and Board of Director meeting dates, as well as the public comment cycle dates. The variance participants may implement the proposed variance only after the Board of Directors' approval and any necessary UNet℠ programming.

Instructions for Completing the Variance Application

The following table provides the application item on the left column, and instructions for providing the requested information in the right column.

Application Item	Instructions for Answering the Application Item
1.a Submitting Members	List the names of all organizations submitting the application. This list may include the name of an organ procurement organization, a transplant center, etc.
1.b Other Members	List the names of all organizations that will be covered by this application. If this is an application to join an existing open variance, you do not need to include the names of Members already participating in the variance. All participants listed should have reviewed the policies relevant to the type of variance that is being submitted for approval. Click on the link below to read the policies referenced above: http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp. Attachment A: Submit documentation explaining any participant's objection to the application. The document can be in the form of a letter, a memo, or a tabular listing of signatories.
1.c Application type	Check the type of application and variance being submitted for approval. If the application is to *amend an existing variance*, you must provide information about the original variance and the changes proposed. Only one application form is necessary, but it must include both sets of information.
1.d National Allocation Algorithms	Check if the proposed variance would alter a national organ allocation algorithm. Attachment B: Submit the proposed alternative allocation system.
1.e Goals	Describe the goals of the variance. If necessary, attach additional pages.
1.f Problem to Address	Submit an evidence-based rationale for the proposed variance as "Attachment C." What are the advantages of the variance? What does the variance provide that the national allocation system does not? If the proposal is an ALU, what is the

		effect of the ALU in relation to each of the six principles for defining "local"? Evidence may include a review of the literature, or data on the existing organ allocation system that show the need for the proposed variance, or both. Anecdotal information, or incident-specific data, may be submitted as supplemental information, not stand-alone. For examples of evidence-based rationales, consider reviewing public comment documents on allocation policy changes. These Committee-sponsored public comment documents can serve as a reference for presenting evidence that support a proposal. Click on the link below to view a new or old public comment document: http://optn.transplant.hrsa.gov/policiesAndBylaws/publicComment/proposals.asp
1.g	***Policy language***	Provide the policy sections that this variance would alter.
1.h	***Open/closed variance***	Check if this is an open or closed variance. If this is an open variance, provide the criteria for other Members to join the variance. For example: • Other Members must be Transplant Hospitals in rural communities • Other Members must join within 60 days of starting this variance.
2	***Research and Evaluation Plan***	The HHS Final Rule states that all variances from the national organ allocation system include a research design component (121.8(g)). The Final Rule interprets alternative allocation systems as experiments, the goal of which is to improve the national system. So, if a proposed variance has the outcome of improving organ allocation, and there is potential for this methodology and outcome to be observed nationally, then elements of the proposed variance could be incorporated in the national organ allocation system. As such, a research design for all proposed variance is critical. In completing this section, consider those measurement indicators as well as the outcomes necessary to demonstrate the success and failure of the proposed variance. Developing research elements such as research hypothesis, goals, and objectives will enable the measurement of the proposed variance. The following are key components of a research plan. Attachment D: Submit a research and evaluation plan with: 1) Goal of Research 2) Objectives of Research (key activities of the research plan; details that operationalize the goals of the research) 3) Statement of the problem (description of the issue posed by the national allocation system; what the variance will resolve) 4) Research questions (questions that guide the study; answers the study will provide) 5) Research hypothesis (expected outcomes of the study) 6) Target Audience (which demographic group the variance will impact) 7) Methodology and study design (details about how the variance will be implemented, instruments that will be used to collect data, what data will be collected, time period for operating the variance, and a variance evaluation plan) 8) Results of the study (presentation of data collected) 9) Analysis of the data (conclusions that can be drawn from data)

	10) Conclusions (information that could be included here are whether the variance should continue as an variance, whether the variance should be incorporated into the national allocation system) 11) Recommendations for future research about the variance (describe any future research plans related to the variance; if the variance will continue after its operating time is complete, then describe any changes that will be made to the methodology, etc., in this future implementation)
2.a Target audience / population	Indicate the group or groups of people, served by the participants submitting this proposed variance, who will benefit from this proposed variance. Will all transplant candidates benefit or only those with certain health conditions? Is the proposed variance attempting to minimize or reduce inequity in the allocation system? Is the target audience transplant candidates in a foreign country due to given the geographic proximity of the local unit to Canada, Mexico, Cuba, or another neighboring country?
2.b Time period for variance	Indicate how long the proposed variance will be in existence. This time frame can serve as a milestone for evaluating the overall impact of the proposed variance. At the conclusion of this time frame, the applicant will need to resubmit the proposed variance for approval to continue the variance. The time frame can be either a specific date or a time period after the variance begins.
2.c Data elements used to evaluate this variance	List existing data elements needed to implement and evaluate the proposed variance. Provide a description and rationale for each data element needed. For example, what data will be collected? What level (OPTN or local) of data is needed? How often must the data be collected or updated? What information will be learned from a given data element? Who will enter these data? What is the relationship between the data element and the goals of the proposed variance?
2.d How these elements will be used	How will the data elements listed in 2.c be used to implement and evaluate the proposed variance? What information will be learned as a result of including these data elements? How will the resulting data be analyzed?
2.e Predicted outcomes from this variance	Describe the possible consequences of the proposed variance. What transplant outcomes of the proposed variance are expected? How will this proposed variance impact organ allocation to, waiting times or priorities of, mortality of, and survival benefit of the candidates served by the participating organizations? What evidence would indicate success of the variance? What outcome would indicate failure of the variance or that the research design would need to be revised to better meet the goals of the variance?