

Office of Regulatory Management
Economic Review Form

Agency name	Department of Corrections
Virginia Administrative Code (VAC) Chapter citation(s)	6VAC 16-20
VAC Chapter title(s)	Regulations for Human Subject Research
Action title	FastTrack
Date this document prepared	10/27/2022

Cost Benefit Analysis

Table 1a must be completed for all actions. Tables 1b and 1c must be completed for actions (or portions thereof) where the agency is exercising discretion, including those where some of the changes are mandated by state or federal law or regulation. Tables 1b and 1c are not needed if **all** changes are mandated, and the agency is not exercising any discretion. In that case, enter a statement to that effect.

- (1) Direct Costs & Benefits: Identify all specific, direct economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (A direct impact is one that affects entities regulated by the agency and which directly results from the regulatory change itself, without any intervening steps or effects. For example, the direct impact of a regulatory fee change is the change in costs for these regulated entities.) When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo. One bullet has been provided, add additional bullets as needed.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
 - (c) Enter the present value of the direct costs based on the worksheet.
 - (d) Enter the present value of the direct benefits based on the worksheet.
- (3) Benefits-Costs Ratio: Calculate d divided by c OR enter it from the worksheet.
- (4) Net Benefit: Calculate d minus c OR enter it from the worksheet.
- (5) Indirect Costs & Benefits: Identify all specific, indirect economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (An indirect impact is one that results from responses to the regulatory change, but which are not directly required by the regulation. Indirect impacts of a regulatory fee change on regulated entities could include a change in the prices they charge, changes in their operating procedures or employment levels, or decisions to enter or exit the regulated profession or market. Indirect impacts also include responses by other entities that have close economic ties to the regulated entities, such as suppliers or partners.) If there are no indirect costs or benefits, include a specific statement to that effect.

- (6) Information Sources: Describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (7) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> • Describe first proposed impactful change here. This proposal is to re-promulgate existing regulations under the proper regulatory authority. <p>Direct Costs: There are no direct costs of the proposed changes. The proposal is to effectuate the move of existing regulations under 6VAC15 to 6VAC16 to comply with a change in the Code of Virginia regarding regulatory authority for regulations governing human subject research within the Department of Corrections. The language of the proposal under 6VAC16 is virtually identical to the existing language of the regulation under 6VAC15.</p> <p>Direct Benefits: The direct benefits are non-quantitative and not tied to economics. The proposed changes realign existing regulations under the proper regulatory authority.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) 0	(c) 0	
Direct Benefits	(b) 0	(d) 0	
(3) Benefits-Costs Ratio	0:0	(4) Net Benefit	0
(5) Indirect Costs & Benefits	There are no indirect costs or benefits associated with the proposed change.		
(6) Information Sources	Internal agency review by Administrative Compliance Unit.		
(7) Optional	The primary change proposed moves existing regulations currently under 6VAC15 to 6VAC16 in order to comply with changes made to the Code of Virginia regarding regulatory authority for human subject research within the Department of Corrections. Previously under the Board of Corrections, the 2020 Acts of Assembly eliminated the existing board and reassigned its		

	responsibilities and authority for certain regulations to the Director of the Department of Corrections.
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Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

This table addresses current requirements and the implications of not making any changes. In other words, describe the costs and benefits of maintaining the current regulatory requirements as is.

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Describe the current requirement associated with the first proposed impactful change described in Table 1a here. <p>The promulgation of the regulations is mandated and the Department is not exercising discretion.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) 0	(c) 0	
Direct Benefits	(b) 0	(d) 0	
(3) Benefits-Costs Ratio	0:0	(4) Net Benefit	0
(5) Indirect Costs & Benefits	There are no indirect costs and benefits.		
(6) Information Sources	Internal agency review by Administrative Compliance Unit.		
(7) Optional	The primary change proposed moves existing regulations currently under 6VAC15 to 6VAC16 in order to comply with changes made to the Code of Virginia regarding regulatory authority for human subject research within the Department of Corrections. Previously under the Board of Corrections, the 2020 Acts of Assembly eliminated the existing board and reassigned its responsibilities and authority for certain regulations to the Director of the Department of Corrections.		

Table 1c: Costs and Benefits under an Alternative Approach

This table addresses an alternative approach to accomplishing the objectives with different requirements. These alternative approaches may include the use of reasonably available

alternatives in lieu of regulation, or information disclosure requirements or performance standards instead of regulatory mandates.

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Describe first alternative proposed impactful change here. <p>The promulgation of the regulations is mandated and the Department is not exercising discretion.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) 0	(c) 0	
Direct Benefits	(b) 0	(d) 0	
(3) Benefits-Costs Ratio	0:0	(4) Net Benefit	0
(5) Indirect Costs & Benefits	There are no indirect costs or economic benefits.		
(6) Information Sources	Internal agency review by Administrative Compliance Unit		
(7) Optional	The primary change proposed moves existing regulations currently under 6VAC15 to 6VAC16 in order to comply with changes made to the Code of Virginia regarding regulatory authority for human subject research within the Department of Corrections. Previously under the Board of Corrections, the 2020 Acts of Assembly eliminated the existing board and reassigned its responsibilities and authority for certain regulations to the Director of the Department of Corrections.		

Impact on Local Partners

- (1) Describe the direct costs and benefits (as defined on page 1) for local partners in terms of real monetary costs and FTEs. Local partners include local or tribal governments, school divisions, or other local or regional authorities, boards, or commissions. If local partners are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.

- (3) Indirect Costs & Benefits: Describe any indirect benefits and costs (as defined on page 1) for local partners that are associated with all significant changes. If there are no indirect costs or benefits, include a specific statement to that effect.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (5) Assistance: Identify the amount and source of assistance provided for compliance in both funding and training or other technical implementation assistance.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	There is no direct cost or economic benefit to local partners. Local governments and others defined as “local partners” generally do not conduct human subject research within the Department of Corrections. Additionally, the regulations for human subject research currently exist under 6VAC15 and have been in effect for many years, with no substantial change in promulgating them under 6VAC16.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) 0
Direct Benefits	(b) 0
(3) Indirect Costs & Benefits	There are no indirect costs or benefits to this change.
(4) Information Sources	Internal review by Administrative Compliance Unit.
(5) Assistance	The Department of Corrections Research Unit is available to provide guidance to those seeking to conduct human subject research within the Department.
(6) Optional	

Economic Impacts on Families

- (1) Describe the direct costs and benefits (as defined on page 1) to a typical family of three (average family size in Virginia according to the U. S. Census) arising from any proposed regulatory changes that would affect the costs of food, energy, housing, transportation, healthcare, and education. If families are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe any indirect costs and benefits (as defined on page 1) to a typical family of three that are most likely to result from the proposed changes.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (5) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 3: Impact on Families

(1) Direct Costs & Benefits	This regulation does not impact families.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) 0
Direct Benefits	(b) 0
(3) Indirect Costs & Benefits	This regulation does not impact families.
(4) Information Sources	Internal review by Administrative Compliance Unit.
(5) Optional	

Impacts on Small Businesses

- (1) Describe the direct costs and benefits (as defined on page 1) for small businesses. For purposes of this analysis, “small business” means the same as that term is defined in §

2.2-4007.1. If small businesses are not affected, include a specific statement to that effect and a brief explanation of the rationale.

- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe the indirect benefits and costs (as defined on page 1) for small businesses that are most likely to result from the proposed changes.
- (4) Alternatives: Add a qualitative discussion of any equally effective alternatives that would make the regulatory burden on small business more equitable compared to other affected business sectors, and how those alternatives were identified.
- (5) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	There is no direct cost or economic benefit to small businesses. The regulations for human subject research currently exist under 6VAC15 and have been in effect for many years, with no substantial change in promulgating them under 6VAC16.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) 0
Direct Benefits	(b) 0
(3) Indirect Costs & Benefits	There are no indirect costs or economic benefits.
(4) Alternatives	There are no effective alternatives. Regulations governing human subject research are applied the same regardless of business size as they impact the treatment and use of individual and their information.
(5) Information Sources	Internal review by Administrative Compliance Unit.
(6) Optional	

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
6VAC16-20	0	62	0	62