Using the OCR Feasibility Process to Select the Best Studies

Nikki Mason, MS, CIP

Director, Office of Clinical Research (OCR)

Services Available from OCR

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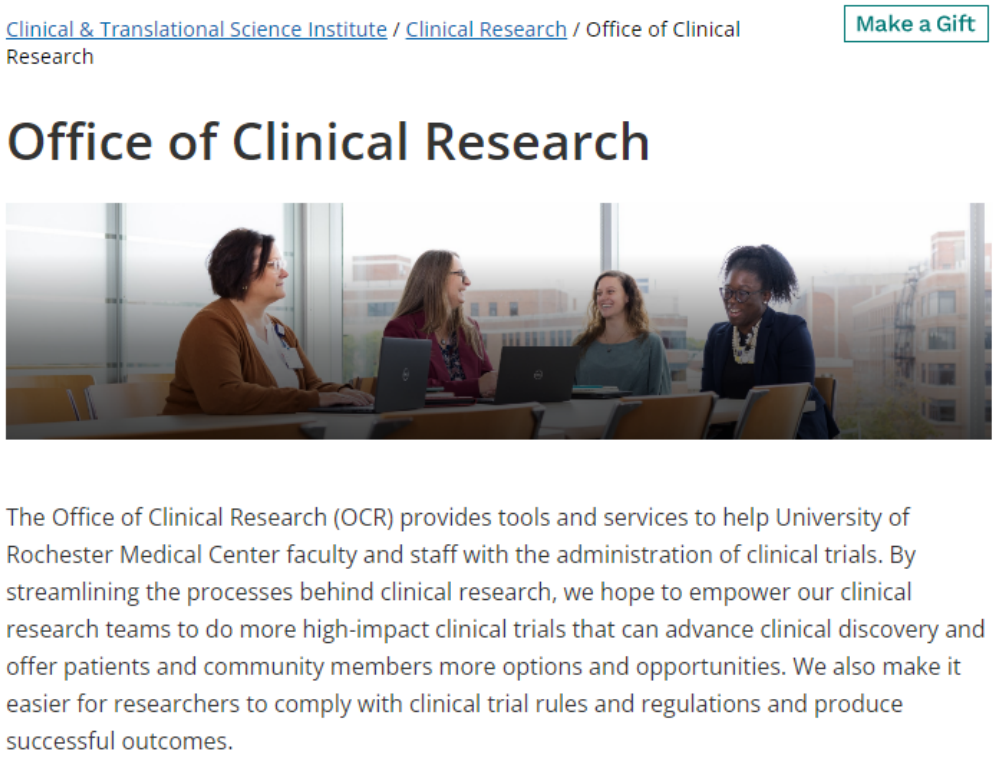
- Feasibility Services



Clinical & Translational Science Institute / Clinical Research / Office of Clinical Research

Make a Gift

Office of Clinical Research

The Office of Clinical Research (OCR) provides tools and services to help University of Rochester Medical Center faculty and staff with the administration of clinical trials. By streamlining the processes behind clinical research, we hope to empower our clinical research teams to do more high-impact clinical trials that can advance clinical discovery and offer patients and community members more options and opportunities. We also make it easier for researchers to comply with clinical trial rules and regulations and produce successful outcomes.

Request Services

Feasibility

Financial

Request Access

OnCore

Participant Payments

Questions?

Email Clinical_Research@URMC.Rochester.edu

OCR Feasibility Assessment Services

The free OCR feasibility process can be requested by anyone!

There are a series of assessments, starting with the simplest and moving to the most complex

1. GO/NO GO checklist - *if the response is GO then move to*
2. Weighted Risk Assessment - *if there is a favorable score then move to, if determined to be needed*
3. Break-even Analysis - *studies that need a deeper dive and clearer financial projections and information*

Go / No Go Checklist

Department

Protocol

- ☐ Indirect no lower than 35% for [illegible]ry
- ☐ No more than 15% withholding by sponsor
- ☐ Study does not have any unallowed platforms and vendors

  ie. Greenphire for participant payments
- ☐ Allows for IDS pharmacy fee(s)
- ☐ If the sponsor is a company we have no record of doing business with in the past, perform quick assessment of financial health of the company (e.g., ask for their financial statements)

Weighted Feasibility Risk Assessment

Under	Reference	Low (1 point)	Medium (2)	High (3)	1,
Sponsor info (c.)	Previous experiences with CRO/Sponsor (investigator side) Yes/no	More than 10 y	5-10 years	less than 5 years	
Sponsor info (c.)	Previous experiences with CRO/Sponsor (OCR Side) Yes/no	More than 10 y	5-10 years	less than 5 years	
Drug or device (i)	Phase	IV - Postmarket	II/III	Pilot or I	
Drug or device (i)	First in Human	**No**	NA	**Yes**	
Drug or device (i)	FDA Approved/CM	**Yes**	NA	**No**	
Competing trials (j)	Competing trials? (	**No**	NA	**Yes**	
Enrollment (k)	Prior enrollment hi	**Yes**	NA	**No**	
Enrollment (k)	Potential Populatic	More than 100	10-100	Less than 10	
Patient info (l)	Number of patients	More than 100	10-100	Less than 10	
Patient info (l)	Source of patients	Clinic, Inpatient	Outpatient, te	Referral, TriNetX, p	
Patient info (l)	Inclusion criteria	Low criteria/mc	Middle of the	Higher # of criteria	
Patient info (l)	Exclusion criteria	Low criteria	Midde of the r	Higher # of criteria	
Patient info (l)	Potential Burden to	Low burden	Moderate bur	Very burdenson, o	
Patient info (l)	Benefit/risk	More Benefit	Mutual benefi	More risk	
Principal Investigator	Prior experiences	More than 10 y	3-10 years	less than 3 years	
PI Availability	Principle Investigator	Very available	Judging a few	Not very available	
Co- or Sub-Investigators	Sub or Co- I	More than 10 y	3-10 years	less than 3 years	
Coordinating Staff Avail	Coordinating staff	Very available	Judging a few	Not very available	
Can Coordinating staff t	coordinating staff	**Yes**	Maybe	**No**	

Break-even Analysis

The Break-even Analysis Feasibility tool consists of three domains:

(1)Protocol Related

(2)Financial

(3)Department Specific

Break-even Analysis

Preliminary Breakeven Analysis

Number of Period: 1

Revenue

Funding Source	Industry	URMC	Sponsor
Schedule of Events Revenue		$41,806	$41,806
Expected Subject Recruitment		2	2
Study Start Fees		$3,972	$3,972
Indirect Rate		35%	35%
Indirect Costs		$14,632	$14,632
Total Per Subject Costs		$60,410	$60,410
Total Revenue Forecasting		$120,820.20	$120,820.20

The sponsor has time constraints placed on Study Start Up Fees. We are assuming the later scenario and have included $3972.00 for the start-up fees.

Variable Costs

Cost Per Screen Failure	$1,618.00
Lab Activation Fee	$1,680.00

$820.

Results:

Breakeven Point (units): 1

Sales volume analysis:

Subject Recruitment	0	0	0	1	1	1	1	1	2	2	2
Subject Per Visit Cost	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10
Fixed costs per period	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44
Variable costs	0.00	430.80	861.60	1,292.40	1,723.20	2,154.00	2,584.80	3,015.60	3,446.40	3,877.20	4,308.00
Total costs	73,704.44	74,135.24	74,566.04	74,996.84	75,427.64	75,858.44	76,289.24	76,720.04	77,150.84	77,581.64	78,012.44
Total sales	0.00	12,082.02	24,164.04	36,246.06	48,328.08	60,410.10	72,492.12	84,574.14	96,656.16	108,738.18	120,820.20
Net profit (loss)	(73,704.44)	(62,053.22)	(50,402.00)	(38,750.78)	(27,099.56)	(15,448.34)	(3,797.12)	7,854.11	19,505.33	31,156.55	42,807.77

$4,308
$58,256
$116,512

Scenario Analysis:

Please note: This analysis does not factor in the time-constraints or accelarated bonuses mentioned in the Accelerated Start-Up and Screening sections. We calculated the estimated FTE cost (overhead) of all personnel and have included it as fixed costs.

Based on this analysis:

If no subjects are recruited into the study, the study will have an estimated deficit of -$73,704.00
If subjects are recruited but not enrolled in the study it will still run at a deficit estimated between -$50,350 and -$62,028

In order to break even, the study will have to recruit and enroll a minimum of two subjects. We can potentially break-even with the enrollment of one subject however this depends on the recruitment of one additional subject in parallel.

How to reach the Office of Clinical Research:
Clinical_research@urmc.Rochester.edu

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Medicine of the Highest Order

thank you!