

**REQUEST FOR BIDS #2023-002
IRB Solution
RESPONSE ADDENDUM #1
July 21, 2022**

QUESTIONS

**Q1: Whether companies from Outside USA can apply for this?
(like, from India or Canada)**

A1: Refer to RFB Section 1.3.2 Eligibility to Submit Responses.

Q2: Whether we need to come over there for meetings?

A2: Refer to RFB Appendix D, Rider A, Business and Performance Reviews

**Q3: Can we perform the tasks (related to RFP) outside USA?
(like, from India or Canada)**

A3: Refer to RFB Appendix D, Rider A, Business and Performance Reviews

Q4: Can we submit the proposals via email?

A4: Refer to RFB Section 1.3.8.

Q5: Could you provide clarification on if this RFP is in respect to only one campus or the entire University System?

A5: Please refer to RFP Section 1.1.3 for details.

Q6: Pricing Question - We understand this to be a multi campus pricing request. Should we provide pricing for each individual campus or for a system wide purchase? What is the volume of active protocols across the whole system and the volume of active protocols at the Southern Maine campus?

A6: We only require separate pricing for University of Maine, Orono and University of Southern Maine.

Q7: Pricing Question - Would you like the pricing for only the University of Southern Maine or all 7 schools connected to the University Systems of Southern Maine? (we could do both).

A7: We only require separate pricing for University of Maine, Orono and University of Southern Maine.

Q8: On average, how many IRB protocols do you have at the University of Southern Maine, and how many across the University of Maine Systems including all seven campuses?

A8: We need further clarification on what is considered to be a distinct protocol (human subject research determinations, exempt, expedited, deviation reports, etc) and including continuing reviews, amendments, or only new protocol submissions?

A8. UM Agree with comment above but ballpark number for UM is 200 new applications (exempt and expedited) per year.

A8. USM also anticipates 200 new submissions of exempt/expedited per year.

Q9: If for the entire University System, does each campus have its own independent IRB and FWA or do they share an FWA and each has its own Registration # and expiration?

A9: USM are the IRB of record for federally funded projects at UMF, UMA, and UMPI.

A9: UM is the IRB of record for UMM and UMFK. UM and USM have their own FWA.

Q10: Is there one primary campus that facilitates reliance agreements with collaborating institutions or does each facilitate its own?

A10: University of Southern Maine and University of Maine each facilitate their own reliance agreements for research with external entities.

Q11: In responding to Appendix H2 (the solution requirements matrix) the RFP asks for an explanation for a Partial or No response. If our answer is a full Yes would the UMS like/permit an explanation of how we achieve that requirement, or do we only enter an explanation for Partial/No responses?

A11: Adding an explanation for Yes responses is fine

Q12: Depending on institutional policies and preferences some clients allow PHI while others prohibit it. What is UMS's position on this. Will you allow PHI in the system?

A12: No

Q13: Can you please provide the most recent annual research volume for the campuses that will initially use the solution?

A13: USM – External grant funding for FY21 was \$25.8M

A13: UMaine – FY21 Total R&D Funding \$133.6M (Total R&D Expenditures - \$179.3M)

Q14: What system are your campuses currently using to track and manage IRB protocols?

A14: Key Solutions- USM only

A14: UM homegrown databases and Word documents for the protocol.

Q15: Why is the University of Maine System considering a move away from its current IRB solution?

A15: We are a public institution which requires public procurement RFPs once the term/renewal term of the agreement is complete.

A14 UM: Looking for a more efficient solution than the current manual process.

Q16: Do any of your campus locations have a firm implementation deadline, blackout periods, or a preferred go-live date with a new IRB solution?

A16: End of December for USM

A16 UM: UM has not implementation date in mind

Q17: What HR system do your campuses use?

A17: Peoplesoft

Q18: Do your campuses anticipate student use of the IRB solution? If so, what enterprise system do they use to manage student data?

A18: Yes—for the second part of the question are you referring to FERPA related data? If so, we do not keep FERPA in our system.

A18: UM agrees with answer above.

Q19: How many active IRB protocols do your campuses typically manage?

A19: We need further clarification on what is considered to be a distinct protocol (human subject research determinations, exempt, expedited, deviation reports, etc) and including continuing reviews, amendments, or only new protocol submissions?

A19: UM agrees with above response. We estimate 200 new protocols per year.

Q20: Do your campuses expect to convert legacy protocol data to the new solution? If yes, what is the volume and character of that data (e.g., all active protocols, all protocols retired in the last two years, etc.)?

A20: USM-Around 600

A20 UM: No.

Q21: Do you have external IRB committee members or external research partners that require access to the system?

A21: Yes, we house two collaborative IRBs with multiple committee members outside the University System.

A21: UM Yes, we have committee members that are external from UMS.

Q22: The RFP specifically asks for an “IRB” solution, but we want to confirm that this is covering only IRB for now, yes? We recognize the requirements ask for the ability to adapt to other

committees (IACUC, IBC, RSC, Col, etc.) but for pricing purposes at this time only IRB is in scope?

A22: IRB solution only

Q23: We received attachments 03, 03a, 04, and 05. Can you confirm there are not other attachments? E.g. 01 and 02. We don't see other attachments on the web site either, but just want to confirm.

A23: All attachments are posted with the RFP on the website.
www.maine.edu/strategic/upcoming_bids.php

Q24: 3.1.1 of Response Format Requirements asks for a PDF copy, but the RFP also indicates that cost tables should be filled out in Excel. In addition to including the Excel files as xlsx files, should we "print" these files into the PDF?

A24: Please submit them in excel versions.

Q25: Please provide the number of new project submissions received by each of the University of Maine and the University of Southern Maine. (Initial submissions only; not amendments, CRs, AEs, closures, etc.)

A25: USM—200 a year

A25: UM – 200 a year