IRB GUIDANCE:
Template Notices for Quality Assessment

Example 1: NOT-For-Cause QAP review:

Dear Dr. _____

As you may be aware, the Institutional Review Board (IRB), Office of Compliance and Audit Services (OCAS) and the Clinical Trials Office (CTO) of Downstate is conducting a pilot Quality Assessment Program (QAP) on research studies on a quarterly basis. Your study (Title, IRBNet#) has been randomly selected for a Not-For-Cause review by the Downstate IRB's Quality Assessment Team.

The purpose of this assessment is to review, inspect and verify the ethical conduct of human research, integrity of data, adherence to the IRB approved protocol, and applicable institutional, state, and federal regulations, policy, and guidance. This program is non-punitive in nature and is designed to be a productive process for investigators while striving for continuous improvement in every area of the research enterprise. If any issues are found, it is important to address them right away and use this as a learning tool to prevent future problems. It is important for investigators and QAP Assessors to be proactive and look for similar issues in other studies. The QAP program is a way to assess readiness for external audits by the FDA, OHRP, NYSDOH, or a sponsor. With advanced planning and strategic corrective actions, the Downstate QAP improves opportunities for continues quality improvement and protection of research participants.

Please familiarize yourself with the standard operating procedures outlined at Step 21 of: Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate website. Step 21 includes posted guidance as well as the forms used for the assessment and CAPA process. The guidance will provide information on the specific procedures that will occur during the QAP, how the study team may prepare for the assessment, study selection criteria, documentation and site review, and how to appeal quality assessment findings. This will allow you to know what to expect and the process that will be followed, thereby, avoiding any surprises. Please ensure all documents and files are readily available and well organized for the team conducting the assessment. Remote procedures may be followed when applicable for the QAP process; however, please plan to identify and reserve appropriate, comfortable space for the QAP review. One person should be identified in advance to be available during the QAP review process. Interviews may be conducted on site, by telephone, or videoconference.

An Associate IRB Administrator will be in contact with you, within the next week to schedule the assessment, including an interview with you and your research staff, and observation of the informed consent process of a potential participant, if applicable. The length of time it will take to complete the assessment will depend on the nature of the research, the number of records

reviewed, the quality of the research records, and the availability of a research participant for the observation of the informed consent process.

We appreciate your cooperation during this phase of the QAP program. Your feedback on this process is very valuable and very much appreciated as the program develops. Please send your feedback or questions to IRB@downstate.edu.

Thank you.

Example 2: For-Cause QAP review:

Dear Dr. _____

As you may be aware, the Institutional Review Board (IRB), Office of Compliance and Audit Services (OCAS) and the Clinical Trials Office (CTO) of Downstate is conducting a pilot Quality Assessment Program (QAP) on research studies on a quarterly basis. Your study (Title, IRBNet#) has been selected for a For-Cause review by the Downstate IRB's Quality Assessment Team.

The purpose of this assessment is to review, inspect and verify the ethical conduct of human research, integrity of data, adherence to the IRB approved protocol, and applicable institutional, state, and federal regulations, policy, and guidance. This program is non-punitive in nature and is designed to be a productive process for investigators while striving for continuous improvement in every area of the research enterprise. If any issues are found, it is important to address them right away and use this as a learning tool to prevent future problems. It is important for investigators and QAP Assessors to be proactive and look for similar issues in other studies. The QAP program is a way to assess readiness for external audits by the FDA, OHRP, NYSDOH, or a sponsor. With advanced planning and strategic corrective actions, the Downstate QAP improves opportunities for continues quality improvement and protection of research participants.

The following concerns promoted the request for a For-Cause Quality Assessment Program (QAP) review *(edit as needed, or provide additional details):*

- Allegation of non-compliance,
- Data discrepancies,
- Documented accounts of possible noncompliance,
- Failure to obtain continuing review or study closure,
- Follow-up from monitoring visit or an external inspection such as FDA, OHRP, NYSDOH,
- Indication of increased risks to study participants,
- Indication or concerns over the ethical conduct,
- Known or suspected issues with study conduct, data integrity, etc.,
- Lack of unreported reportable events,
- Reason to need verification that research is being conducted in accordance with the IRB approved protocol,
- Report of concern from a 3rd Party,

- Research Participant or Family Member complaint,
- Response to a substantive written or verbal allegation,
- Response to an indication of non-compliance,
- Request by the Reviewing (External) IRB,
- Suspected research misconduct, serious or continuing non-compliance, or unanticipated problem
- When safety warnings are issued by the FDA, or
- When there is a change in FDA labeling that increases risks.

Please familiarize yourself with the standard operating procedures outlined at Step 21 of: Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate website. Step 21 includes posted guidance as well as the forms used for the assessment and CAPA process. The guidance will provide information on the specific procedures that will occur during the QAP, how the study team may prepare for the assessment, study selection criteria, documentation and site review, and how to appeal quality assessment findings. This will allow you to know what to expect and the process that will be followed, thereby, avoiding any surprises. Please ensure all documents and files are readily available and well organized for the team conducting the assessment. Remote procedures may be followed when applicable for the QAP process; however, please plan to identify and reserve appropriate, comfortable space for the QAP review. One person should be identified in advance to be available during the QAP review process. Interviews may be conducted on site, by telephone, or videoconference.

Add the following paragraph, as applicable:

For this review, the (name of reviewing/external) IRB requested the Downstate IRB review the following documents and information to make a decision regarding non-compliance:

- Include relevant participant selection and/or percent of records to be reviewed where applicable
- Current Protocol in use by site
- Current Consent Documents in use by site
- Investigator/Study Team Training Documentation
- Source Documentation (Specify):
- Other (e.g., Relying Institutions Policies, Study Manuals, Investigator Brochures, Notes to file, Adverse Event and Deviation logs, etc.) (Specify):
- Additional information (Specify)

If the review has already started without notice, include the following:

An Associate IRB Administrator has started this assessment, which may include an interview with you and your research staff, and observation of the informed consent process of a potential participant, if applicable. The length of time it will take to complete the assessment will depend on the nature of the research, the number of records reviewed, the quality of the research records, and the availability of a research participant for the observation of the informed consent process.

If notice is given, include and edit as applicable:

An Associate IRB Administrator will be in contact with you, within the next week to schedule the assessment, including an interview with you and your research staff, and observation of the informed consent process of a potential participant, if applicable. The length of time it will take to complete the assessment will depend on the nature of the research, the number of records reviewed, the quality of the research records, and the availability of a research participant for the observation of the informed consent process.

Always include:

We appreciate your cooperation during this phase of the QAP program. Your feedback on this process is very valuable and very much appreciated as the program develops. Please send your feedback or questions to IRB@downstate.edu.

Thank you.

References

IRB GUIDANCE: Quality Assessment Program (Pilot Phase)

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Review and Approval History

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	Yes	No		
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